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# *The Maryland Pharmacist*

VOL. 69

January, 1993

No. 1



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

January 1993

Volume 69

Number 1

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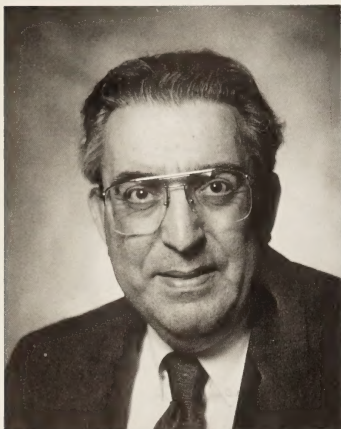
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# President's Commentary

*Nicholas C. Lykos, P.D., President*



Ethics is that branch of philosophy concerned with what is morally good or bad, right or wrong. Ofttimes, what is considered ethical behavior may, in fact, be illegal. Witness, for example, the debates raging in Michigan over Dr. Kevorkian and his "suicide machine." To many, the right to die with dignity is an ethical decision to be made by each individual; to others, suicide of any form is immoral. Assisting in suicide regardless of the reason, especially by a health professional, is considered by many to be morally wrong or unethical.

Each person's ethics develop as we grow and reach maturity. Our first experience with ethics begins with obedience and punishment as infants and children. Studies of parents and their verbal interactions with children show that the most frequently used word is "no." The next stage of moral and ethical development can best be expressed by "you scratch my back and I'll scratch yours," as we attempt to meet our own needs through negotiation and behavior bartering. Anyone with children know how quickly kids become skillful at obtaining what they want with good behavior (and a good old-fashioned temper tantrum when that doesn't work!). As we grow older, we begin to select ideals, seek approval from peers, and develop a sense of society's expectations as our social contacts expand.

Ethics and ethical behavior were a major focus of the recent presidential campaigns. Questions of ethics were raised about both candidates' past behavior: "How much was Bush" in the loop? Did Clinton commit adultery?" President-elect Clinton has gone so far as to proposed a strong "ethical standard" for his political appointees that would prohibit them from using their positions to lobby the government should they choose to leave his administration.

In mid-December, delegates at the American Medical Association annual convention in Nashville established a policy position soundly based on ethical principles. The delegates voted that it was both unethical and inappropriate for physicians to refer patients to medical facilities where the physician has a vested financial interest. The AMA delegates believed that, although a physician had a legal right to direct patients to laboratories, diagnostic clinics, pharmacies, etc. that the physician either owned or obtained financial compensation, doing so is contrary to the moral relationship between the physician and his or her patient. Interestingly, this decision came shortly after a number of government studies showing that physicians with financial interests had a significantly higher rate of additional health procedures.

Pharmacists make many daily decisions that directly effect our patients' health and well-being. Public perception of our honesty and integrity in making those decisions continues to run high; the most recent Gallup Poll again reaffirmed that the pharmacist is looked upon as the most trusted of all professionals.

The pharmacist, as a person bringing his or her own ethical and moral background to each decision, also bases those daily decisions on the collective ethics of the profession. How many times have you stopped to consider, even for a moment, "Is this a prescription that I will dispense?" When you counsel a patient, don't you quickly and quietly balance your knowledge about the drug and disease in addition to what you know about the patient's background



# Pharmacists Again Earn Public's Trust

For the fourth consecutive year, pharmacists again led a public opinion poll conducted by the Gallup Organization rating the honesty and ethical standards of 25 professions.

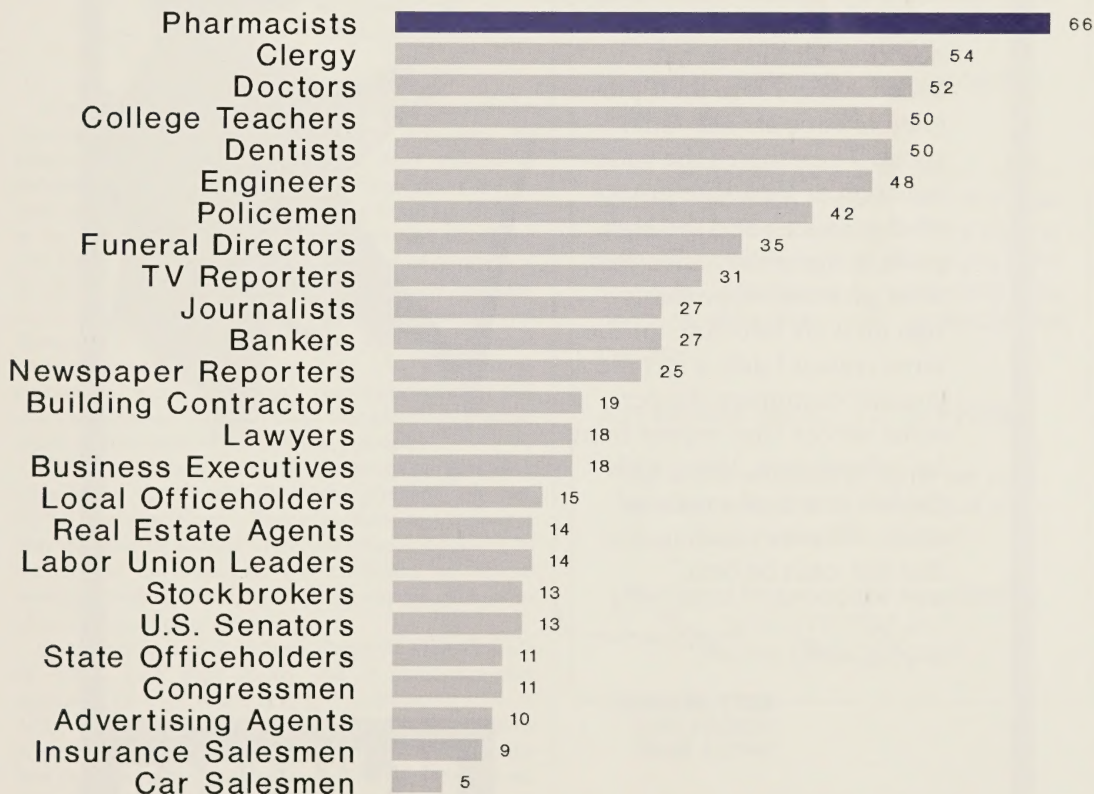
In the recently released Gallup Poll, two-thirds of Americans rated druggists/pharmacists as having "very high" or "high" standards of honesty and ethics, making them the most respected of the diverse sampling of professions evaluated. Gallup conducted the poll June 26 through

30 of 1992 by asking "How would you rate the honesty and ethical standards of people in these different fields -- very high, high, average, low, or very low?"

The pharmacists' 12-point margin over members of the clergy for the top position is the highest in the poll's history, according to the Gallup Organization, and was one of only two categories that received substantially higher ratings -- a six percent increase -- compared to the

1991 poll. College teachers' rating climbed five percent over last year.

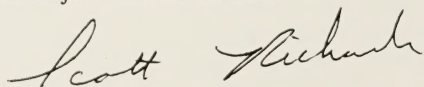
Elected officials in federal and state government received their lowest rating in 16 years of polling on the subject. Only 13 percent of Americans think U.S. senators have high standards, compared to 24 percent in 1990 and 19 percent in 1991. Barely one in 10 (11 percent) rate members of the House of Representatives highly, an eight-point decline from 1991. **R**



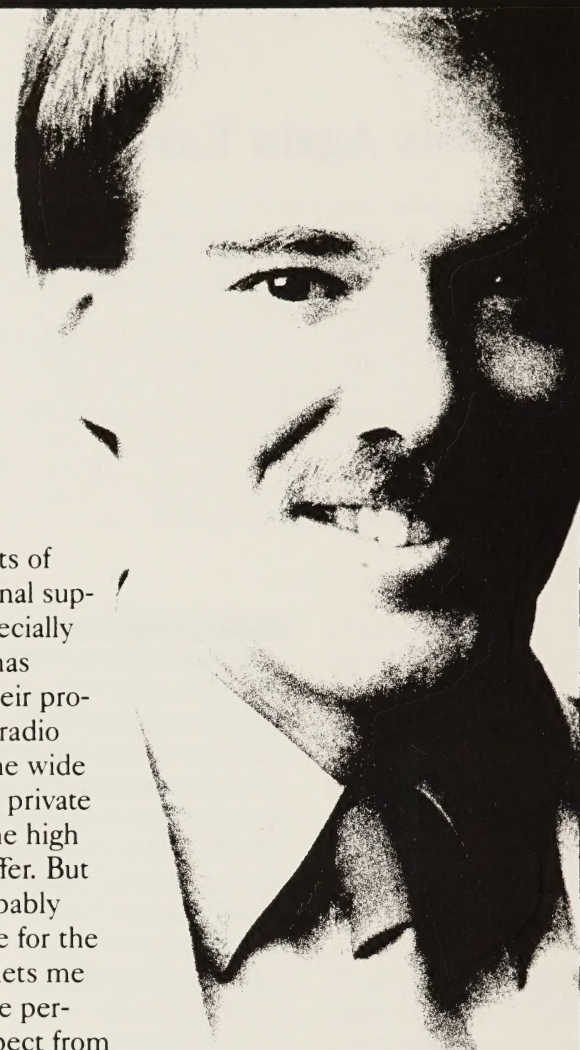


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and profile? As you well know, it is very possible that for one patient you would stress a particular subject where, if it were another patient, the subject might be totally avoided. Personal and professional ethics determine what is morally right or wrong.

In February 1990, MPhA leadership met in a strategic planning session to examine the future of the Association. Part of that meeting resulted in a revision of MPhA's bylaws, including the revision of MPhA's mission statement. The officers and trustees drafted a mission statement that emphasized providing and encouraging the best pharmacy care available to our patients. That statement reads:

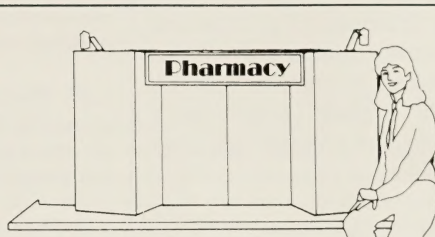
*The mission of MPhA is to represent and serve pharmacists and to promote the highest standards of professional practice in Maryland.*

A major objective of MPhA's strategic plan was the development of pharmacy practice standards by pharmacists for pharmacists. After many months of dedicated effort by the Professional Affairs Committee, an open discussion of the proposed principles and guidelines at the 1992 Mid-Year Meeting, revisions and redrafting and finally approval by the MPhA Board of Trustees, I am pleased to announce the publication of our *Principles and Guidelines for Pharmacy Practice in Maryland*. This document is included in this month's journal as a special pull-out section beginning on page 13. I encourage everyone of you to thoroughly read this document and make a concerted effort to ensure that pharmacy practice meets and/or exceeds this practice principles.

Don't think, however, that one document can guarantee ethical and appropriate pharmacy practice. In fact, MPhA has established a Principles Revision Committee that will annually address additional areas that need to be included in our *Principles and Guidelines* as well as revisiting existing principles that will require changes as pharmacy practice evolves.

Our *Principles and Guidelines*, along with MPhA's Code of Ethics (see page eight), are a profession-wide statement of what is the best that pharmacists have to offer. It is the responsibility of each individual pharmacists, MPhA member or not, to strive to give the best and most ethical pharmaceutical care possible to our patients and clients.

R



## *Get Pharmacy's Message Across*

Have you been asked to make a presentation before the local PTA about drugs?

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# Maryland Pharmacists Association Code of Ethics

## Preamble

These principles of professional conduct are established to guide pharmacists in relationships with patients, fellow practitioners, other health professionals, and the public.

**A Pharmacist** should hold the health and safety of patients to be of first consideration and should render to each patient the full measure of professional ability as an essential health practitioner.

**A Pharmacist** should never knowingly condone the dispensing, promoting, or distributing of drugs or medical devices, or assist therein, that are not of good quality, that do not meet standards required by law, or that lack therapeutic value for the patient.

**A Pharmacist** should always strive to perfect and enlarge professional knowledge. A pharmacist should utilize and make available this knowledge as may be required in accordance with the best professional judgment.

**A Pharmacist** has the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. A pharmacist should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession.

**A Pharmacist** should seek at all times only fair and reasonable remuneration for professional services. A pharmacist should never agree to, or participate in, transactions with practitioners of other health professions or any other person under which fees are divided or that may cause financial or other exploitation in connection with the rendering of professional services.

**A Pharmacist** should respect the confidential and personal nature of professional records; except where the best interest of the patient requires or the law demands, a pharmacist should not disclose such information to anyone without proper patient authorization.

**A Pharmacist** should not agree to practice under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause a deterioration of the quality of professional services, or that require consent to unethical conduct.

**A Pharmacist** should strive to provide information to patients regarding professional services truthfully, accurately, and fully and should avoid misleading patients regarding the nature, cost, or value of these professional services.

**A Pharmacist** should associate with organizations having for their objective the betterment of the profession of pharmacy and should contribute time and funds to carry on the work of these organizations. **R**

# Improving Patient Medication Compliance

## *The Results of Schering Report XIV*

*Jack Robbins, Ph.D., Pharmacy Affairs Director, Schering Laboratories*

Patients are failing to take their medications as prescribed at an alarming rate, with serious consequences to themselves, patients, physicians, pharmacists and the nation's rapidly escalating health care costs, according to a new, independent survey commissioned by Schering Laboratories. When people don't take their prescribed medicines properly, they are less likely to get better. In the long run, these patients will require greater amounts of health care -- often including hospitalization -- when simply taking their medications as directed would have led to a rapid recovery.

Schering Report XIV, "Improving Patient Compliance: Is There a Pharmacist in the House?," explores the evidence and consequences for patients, physicians and pharmacists -- the three groups directly involved -- and suggests that patient compliance has not improved perceptibly since 1987, when Schering Report IX first examined the problem. The study was based on interviews with 2,000 adults representing a demographic profile of the U.S. population.

The nation's health care bill passed the three-quarters-of-a-trillion-dollar mark last year, and a large part of that cost comes from improper patient compliance. This is not just a dollars-and-cents issue; people who are involved -- patients, physicians and pharmacists. Patients pay the toll in prolonged sickness, hospitalization, lost workdays, higher insurance costs and even death. Doctors are baffled by the apparent ineffectiveness of treatment, and find that draining. Pharmacists, because of poor patient compliance, fill and refill fewer prescriptions than they should, and they observe how their patients fail to benefit from the therapies prescribed for them.

### **Defining Non-Compliance**

In defining patient non-compliance, there are three facets of improper medication use that must be considered: when patients get a prescription from the doctor but do not have it filled; when patients do not take the medication as prescribed; when patients do not follow instructions and fail to have the prescription refilled.

Examining physicians' prescribing patterns, the survey noted that eight of 10 adult Americans (79 percent) visited a doctor in the past 12 months. Women (86

percent) visited doctors more often than men (72 percent), and patients over age 55 (87 percent) visited doctors more often than those under 55 (77 percent).

Why are so many patients crowding doctors' waiting rooms? Most often, it was for a routine physical (40 percent), or to follow up on an existing condition (33 percent). One in five (21 percent) sought help on a "new problem," with younger patients most likely to cite a "new health problem."

Surprisingly, not every visit leads to a written prescription. Barely half (52 percent) of physician visits resulted in a prescription. But of those patients who did receive a prescription, 39 percent of the time they received two or more.

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***The average pharmacy loses about \$51,000 per year from potential patients who don't have their prescriptions filled***

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The survey also asked patients who received prescriptions how much time the doctor spent counseling them about the medications. Some 88 percent reported that the doctor told them "how much to take or apply each time" and the same percentage recalled the doctor telling them "how often to take it." Somewhat fewer (81 percent) said they were told "how long to continue taking it."

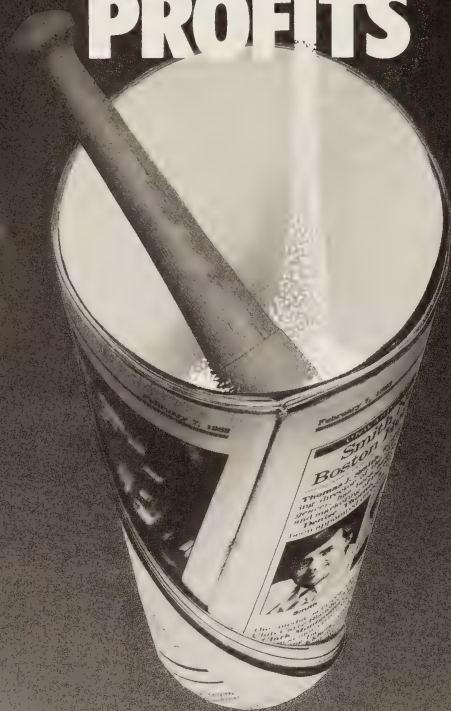
How do these replies compare with results of the Schering Report five years ago? The rate of medication advice by physicians fell for all three factors -- from 92 percent to 88 percent for information on both dosage and frequency, and from 87 percent to 82 percent on how long to continue taking the medicine.

Based on these data, the Schering Report suggested that doctors are even busier today, with less time for patient counseling. This means that the pharmacist's role in filling the counseling gap is even greater than ever.

The economic consequences to pharmacists resulting from patients failing to fill their initial prescriptions -- 8.7 percent of those interviewed -- are startling. Based on the

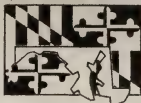


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approximately 1.6 billion prescriptions written each year - with an average retail value of \$20 -- that's a shortfall at the pharmacy counter of about 140 million prescriptions worth \$2.8 billion.

Dividing that figure equally into the nation's approximately 55,000 pharmacies means that each pharmacy is losing up to \$51,000 per year, or about \$1,000 per week, from potential patients who don't have their prescriptions filled.

The Schering Report noted that the number of patients neglecting to fill their prescriptions could possibly be much higher than people admit. What is clear, however, is that more patients today are admitting that they are not bothering to fill their prescriptions than a short five years ago when the figure was only seven percent. Perhaps there may be a link in the drop in prescription-filling with the reported drop in the level of physician counseling.

#### Reasons for Non-Compliance

What reasons did these people give for not filling their prescriptions? The reasons given most often were: "I didn't need the medicine because the condition improved or disappeared on its own....I still have enough of that medicine from a prior prescription....The doctor gave me some samples, and I'll fill the prescription after I have used up the samples."

When patients do have their prescriptions filled, are they loyal to their regular pharmacist? Four out of five (81 percent) say they "usually have (their) prescriptions filled at the same pharmacy all of the time."

The greatest opportunity for the pharmacist to counsel patients is when they personally visit the pharmacy to drop off -- and especially to pick up -- prescriptions. Based on the people interviewed, seven out of 10 (69 percent) personally brought their most recent prescription to their pharmacy, and also picked it up.

A patient picking up a prescription has the right to expect professional counseling about the proper way to take the medication, as well as possible side effects, interactions and anything else that patient should know about the medication prescribed. Among those who picked up their prescriptions, only slightly more than half (52 percent), receive the medication from the pharmacist,

while 48 percent received it from a clerk.

The survey cited concern about the consistency with which pharmacists counsel patients on how and when to take medications. Pharmacist's counseling is vital because patients often become flustered in the doctor's office and forget or misremember any instructions the doctor may have given them.

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*Significantly fewer patients reported that they received counseling from the pharmacist than five years ago. This fact has serious ramifications for pharmacy's attempts to implement pharmaceutical care*

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The survey results show that counseling by pharmacists is also distressingly sparse. Only 25 percent of patients were told how often to take the medicine, with the same percentage being told how much to take or apply each time. Only 21 percent received instructions on how long to continue taking their medication.

There has been substantial change since the first Schering Report on patient counseling five years ago. The rate at which information is given to patients by pharmacists about frequency of medicine has fallen 15 percentage points, from 40 percent to 25 percent; on dosage by 18 percentage points, from 43 percent to 25 percent; and on duration by 15 percentage points, from 36 percent to 21 percent.

While the amount of information pharmacists are giving -- or most often not giving -- may be disappointing, their patients do not seem to mind at all. Seventy-four percent of people interviewed said they were completely satisfied with the verbal and written instructions provided by their pharmacist.

The physical setting of the pharmacy itself may discourage the interchange between pharmacist and patient -- no privacy, too many people around, too much chance for embarrassment. There might be more communication if separate consulting areas, now found in only a few pharmacies, became more common.



Interestingly, only three percent of the people interviewed reported that when they do speak to the pharmacist, the interchange takes place in a "separate location set aside for consulting." Fifty percent felt that a private consulting area in the pharmacy would be desirable, with women and younger patients the most fervent proponents.

While most patients appear to be satisfied with the amount of information provided by pharmacists, when, if ever, do patients think the pharmacists "should talk to them personally about their prescription?"

Twenty-seven percent of the patients said every time a prescription is filled. The remainder put the initiative either on the patient, with 36 percent saying only if the patient asks; or on the pharmacist, with 32 percent saying only when the pharmacist thinks it is necessary.

To find what value patients place on pharmacists' time, the survey asked, "How much should be added to the cost of the prescription as the pharmacist's consulting fee, if a law required pharmacists to consult with patients." The most popular answer was, as anticipated, "nothing" (64 percent), followed by "I don't know" (23 percent). Among patients who responded with a dollar amount, the average was \$2.17, which while a low figure, suggests that patients do place a value on the pharmacist's counseling role.

To gauge how patients feel about the pharmacist as a professional health care counselor, they were asked whether they agreed or disagreed with these statements:

*The pharmacist's verbal instructions are very clear and complete.* Almost two-thirds (63 percent) strongly agreed.

*"The pharmacist is usually busy, but will spend as much time with me as I need to discuss the prescription."* Just over half (52 percent) strongly agreed.

Pharmacists are indeed ready to fill the breach in the doctor's instructions, they have not sufficiently and successfully demonstrated this to their patients.

*Continued on page 22....*

### **Tips for Improving Patient Compliance**

- Come out from behind the pharmacy counter and talk face-to-face with patients. Don't leave it to a clerk.
- Make sure the atmosphere is congenial. Set aside a separate counseling area.
- Don't be shy about the "personal" aspects of the patient's malady as they relate to the medication. Patients aren't shy.
- Keep in mind a mental checklist of the "basics" -- dosage, frequency and duration, and add side effects and possible food and drink interactions.
- Alert patients to possible interactions with other medications by using the pharmacy's computer records on other drugs they might be taking.
- Provide written instructions on medications and tell patients you will be glad to answer any questions.
- Use brightly colored precaution labels on prescription containers.
- Display, near the register, items that remind people when to take medication: "counter caps" or medicinal bottles with digital alarms.
- Update patients' computer records after speaking to them.
- Offer to participate in "brown bag" screenings organized by senior citizen centers where participants bring all their medications to be reviewed.
- Develop a program to remind patients about prescription refills.



*Principles and Guidelines  
for Pharmacy Practice  
in Maryland*



*In 1991, the Maryland Pharmacists Association took the first steps in developing professional principles and guidelines for practice by pharmacists in Maryland. The House of Delegates, MPhA's policy body, believed that it was up to the profession through its statewide organization, to take the lead in establishing what is appropriate pharmacy practice. This document, **Principles and Guidelines for Pharmacy Practice in Maryland**, comprises the first official publication of that effort.*

*These Principles are not intended to codify the current practices of pharmacy, nor do they describe the best practices of pharmacy. Rather, they are intended to point to the better practices reasonably to be expected, considering the education of current pharmacists, the status of technology, and the willingness of the customer base to pay for it.*

*State and federal laws and regulations governing the control of drugs and devices form the base from which these principles and guidelines to better pharmacy practice ascend.*

*The Guidelines provided for the Principles are not mandates or requirements; they are, instead, recommendations. They exist solely to facilitate the compliance of pharmacists with the principles. Guidelines are useful suggestions in achieving the principles but are not necessarily the only route to achievement.*

*MPhA's **Principles and Guidelines for Pharmacy Practice in Maryland** is a living document, intended to be reviewed, added to, or changed every year. Suggestions for additional principles should be directed to the MPhA Principles Revision Committee at the MPhA headquarters.*

**1991-1992 Professional Affairs Committee Members:** William Heller, Chairman, Calvin Alt, Jr., Robert Beardsley, Alisa Billington, Joe DeMino, Donald Fedder, Jerome Fine, Kathleen Gauthier, Vince Ippolito, Lisa Langer, Gary Magnus, Penney Miller, Gail Rosen, Gracemarie Smith, Phillip Weiner.

**1992-1993 Principles Revision Committee Members:** Ilene Zuckerman, Chair, Bruce Greenberg, Vince Ippolito, Gail Rosen, Gracemarie Smith.

## ***Administrative Principles***

**AD 0192. Pharmacy services shall be performed under the direction of a licensed pharmacist (the director).**

### *Guidelines*

- a. The director is thoroughly knowledgeable about the professional practice principles.
- b. The director is responsible for adhering to the professional practice principles.
- c. The director is responsible for adhering to all applicable laws and regulations.
- d. The director is responsible for assuring the ongoing monitoring of quality of care.

**AD 0292. The director or his/her designee shall be responsible for the supervision of ancillary pharmacy personnel (e.g., clerks, technicians).**

### *Guidelines*

- a. If there are three or more employees, written job descriptions should exist for ancillary positions. These job descriptions should clearly delineate the scope of responsibilities.
- b. If there are three or more employees, written policies and procedures should exist for recruitment, hiring, discipline, training, and discharge of ancillary personnel.

## ***Controlled Substances Principles***

**CS 0192. The pharmacist shall observe federal/state laws for initial and biennial inventory of controlled substances.**

### *Guidelines*

- a. Standardized forms are available to aid in the inventory process and should be used whenever possible.
- b. To help ensure accuracy, CDS inventories should be completed by at least two people, one of whom is a pharmacist.
- c. The pharmacist shall countersign all counts with date and time the inventory is begun and finished.
- d. Whenever possible, the pharmacist should maintain a perpetual inventory, or perform regularly scheduled inventories if theft is a problem or controlled dangerous substances have multiple staff access.

**CS 0292. The pharmacist shall observe all federal and state laws in maintaining complete and accurate records of receiving and dispensing transactions.**

### *Guidelines*

- a. Keep all Schedule II drug order forms in one location with access limited to authorized personnel only.
- b. Keep in an area separate from the Schedule II order forms a record of the serial numbers of the order forms on hand and the date the order forms were requested and received.
- c. A pharmacist should sign or countersign the DEA order form designating the receipt of all Schedule II medications with date and time of receipt.

**CS 0392. The pharmacist shall observe federal/state laws in the storage of controlled dangerous substances (CDS).**

### *Guidelines*

- a. If a safe or locked cabinet is used to store controlled dangerous substances, access to the safe combination or cabinet key should be limited to the pharmacist on duty or authorized personnel.

**CS 0492. The pharmacist shall observe federal/state laws in filling a written CDS prescription, noting particularly those for partial filling of a CDS prescription.**



**CS 0592. The pharmacist shall observe all federal and state laws in filling an oral emergency CDS prescription.**

*Guidelines*

- a. The pharmacist should verify all phoned-in prescriptions when the caller or physician is unfamiliar by a return phone call to the prescriber's publicly listed phone number.

**CS 0692. The pharmacist shall observe federal/state laws in transferring Schedule III-V prescription information between pharmacies.**

**CS 0792. The pharmacist shall observe federal/state laws in reporting the theft of controlled dangerous substances.**

**CS 0892. The pharmacist shall observe federal/state laws in handling altered or forged controlled dangerous substances prescriptions.**

*Guidelines*

- a. The pharmacist should verify phoned-in prescriptions when the caller or physician is unfamiliar by a phone call to the prescriber's publicly listed phone number.
- b. The pharmacist should exercise professional judgment in doubtful situations where verification of the prescription is impossible. The pharmacist may choose to advance a minimum amount of medication to alleviate problems of the patient until the prescription can be verified. The pharmacist may also choose to refuse to fill the prescription entirely.
- c. If the situation warrants, the pharmacist should contact the police or the Division of Drug Control.
- d. Pharmacists should develop a chain call system whereby local pharmacies keep each other informed of stolen prescription pads reported by physicians, etc.
- e. The pharmacist should keep a physician file in the pharmacy on physicians who are unfamiliar to the pharmacist or have had to be called to check verification of a prescription. It may be helpful to keep photocopies of rarely seen signatures.

**CS 0992. The pharmacist shall observe federal/state laws in disposing of outdated controlled dangerous substances.**

*Guidelines*

- a. The pharmacist should keep a log of all controlled dangerous substances wasted or destroyed (must be signed by two responsible agents, one of whom is a pharmacist).

- b. The pharmacist shall keep all controlled dangerous substances to be returned or destroyed in a safe or locked cabinet until it is determined what course of action is to be taken for disposition.

## ***Equipment Principles***

**EQ 0192. The pharmacist shall have suitable, up-to-date reference materials.**

*Guidelines*

- a. Adequate space and appropriate drug use information resources for the provision of drug information to patients and prescribers is necessary.
- b. A pharmacy should have mechanisms for providing written drug use information to the public such as patient information leaflets, as well as having one or more patient oriented texts placed in an accessible place.
- c. A pharmacy should have a reference library that includes texts or computerized data bases on: pharmacology, drug interactions and incompatibilities, drug identification, laws and regulations, nonprescription drugs, adverse drug reactions, and other information appropriate to the patient population served.

**EQ 0292. The pharmacy shall have suitable data processing equipment.**

*Guidelines*

- a. Data processing equipment is desirable for: patient medication profiles, patient billing procedures, drug use review and drug interaction information. It should be capable of providing appropriate drug use information for the patient. The equipment should also be able to maintain drug inventories and interface with other computerized systems to allow for third party billing procedures and communication with other health professionals or medical databases.

## ***Patient Profile Principles***

PP 0192. A medication profile shall be maintained on all patients.

### *Guidelines*

- a. Patient information to be maintained should include:
  1. Name, address, phone number, birthdate, and gender.
  2. Significant individual history, including disease state(s), allergies and drug reactions.
  3. Pharmacist's comments relevant to the patient's drug therapy.
  4. Insurance information, discounts (if applicable).
- b. Medication history to be maintained should include:
  1. Prescription history - drug, dosage form, strength, quantity, manufacturer or distributor, name of prescriber, and refill history.
  2. OTC history.
  3. History of any associated medical devices.

PP 0292. With the consent of the patient, which may be given in advance, all or portions of the patient profile information may be provided to others who are responsible for the patient's care.

### *Guidelines*

- a. Those who may be allowed to have access to the patient's profile, with the patient's permission, include:
  1. The patient's care-giver.
  2. Prescribers whose prescriptions for the patient are current.
  3. Any additional medical care-giver named by the patient.
  4. Any third-party reimbursement program designated by the patient.

## ***Patient Counseling Principles***

PC 0192. The patient has a right to expect appropriate counseling from the pharmacist prior to the purchase of an OTC drug or the dispensing of a prescription drug, and subsequent counseling as needed, particularly at the time of any subsequent purchase or dispensing.

PC 0292. The pharmacist has a right to charge for this educational, patient-protection activity separately from the costs of the acquisition, storage and selling of the drug as a commodity.

PC 0392. Counseling is a two-way communication: the pharmacist learns about the patient and teaches the patient about the drug. The essential parts of this two-way communication, which is necessarily oral to begin with, are reduced to writing in the pharmacist's patient record and in the written drug use information provided to the patient.

PC 0492. Pharmacist-patient communication does not occur in a vacuum, but involves the prescriber(s) also. The amount and depth of information, although tailored to the needs of the patient at the particular point in time, should be generally consistent with the amount and extent of information generally expected of pharmacists by physicians, dentists, and other prescribers.

PC 0592. In observing these principles the pharmacist shall, before a prescription is filled or delivered to the patient, screen for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-food and drug-drug interactions (including serious interactions with OTC drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

PC 0692. The pharmacist must offer to discuss with the patient or care giver (in person, whenever practicable, or through access to a telephone service which is toll-free for long distance calls) matters which in the exercise of the pharmacist's professional judgment are significant.

### *Guidelines*

These matters may include, but are not limited to:

- a. The name and description of the medication.
- b. Dosage, route of administration, and duration of drug therapy.



- c. Special directions and precautions for preparation, administration and use by the patient.
- d. General use (patient-specific use where indicated by the prescriber) and expected actions.
- e. Common and/or severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
- f. Techniques for self-monitoring drug therapy.
- g. Proper storage of the medication.
- h. Prescription refill information.
- i. Action to be taken in the event of a missed dose.

**PC 0792. The pharmacist must make a reasonable effort to obtain, record, and maintain pertinent information about the patient.**

#### *Guidelines*

Pertinent information includes, but is not limited to:

- a. Name, address, telephone number, birthdate, gender.
- b. Significant individual history, including disease state(s), allergies and drug reactions, and a comprehensive list of medications and relevant devices, including the prescribers' names.
- c. Pharmacist comments relevant to the patient's drug therapy.

**PC 0892. The labels of the prescription container must, at a minimum, bear the following information:**

#### *Guidelines*

- a. Name, address, and telephone number of the pharmacy.
- b. Date of dispensing.
- c. Serial number of the prescription.
- d. Patient's full name.
- e. Name of the drug, strength and amount dispensed.
- f. Prescriber's name.
- g. Directions to the patient for use of the drug.
- h. Precautionary information (may use auxiliary labels).
- i. Initials or name of the responsible pharmacist.
- j. Refills allowed.
- k. Expiration date.

**PC 0992. Supplementary written information such as patient information leaflets should be provided as necessary to supplement and reinforce oral counseling. Each year the Maryland Pharmacists Association in cooperation with the Medical and Chirurgical Faculty of Maryland will identify a dozen drugs/drug families that appear to need special emphasis that year with written information supplementation in Maryland.**

**PC 1092. The pharmacy should have a designated patient counseling area.**

#### *Guidelines*

- a. A private area should be provided that allows a pharmacist to counsel the patient on a "face to face" basis. The patient profile should be readily available, as well as drug use information references and visual aids. If a private area is not possible or appropriate, the pharmacist shall nevertheless make a reasonable effort to counsel the patient.

## ***Drug Product Control Principles***

**DP 0192. Drug products shall be ordered only through legitimate channels and sources of supply.**

**DP 0292. Drug products shall be given a preliminary inspection as soon as possible after receipt on site.**

### *Guidelines*

- a. General Inventory and Schedules III, IV and V controlled dangerous substances may be given a preliminary inspection by a pharmacist or ancillary personnel.
- b. Schedule II CDS may be received by a pharmacist only.
- c. General Inventory - all drug products shall be checked against the invoice or packing slip for errors, omissions or damage, which are to be reported to proper personnel. Products shall be stored promptly and the inventory adjusted appropriately.
- d. Schedule III, IV, V - all items shall be checked against the invoice or packing slip for errors, omissions, or damage which are to be reported to a pharmacist. Products shall be stored promptly and the inventory adjusted appropriately.
- e. CDS Schedule II - a pharmacist shall check all items against the invoice or packing slip for errors, omissions, or damage, complete the US DEA Form 222, and place the inventory into storage immediately. Errors, omissions, or damage must be reported to the supplier immediately and proper documentation noted.

**DP 0392. A drug product shall be stored under the conditions of light, time, temperature and humidity as directed by the United States Pharmacopeia or, for a particular brand, by the manufacturer.**

**DP 0492. A controlled dangerous substance shall be stored under conditions of security directed by federal/state laws.**

**DP 0592. The person responsible for filling a prescription order shall be a pharmacist.**

### *Guidelines*

- a. Any ancillary personnel are the responsibility of and responsible to the pharmacist.

**DP 0692. The prescription medication shall be dispensed in a container meeting the requirements for patient storage of that drug.**

### *Guidelines*

- a. Original - The prescription may be dispensed in its original container, if appropriate.
- b. Non-Original - Must meet USP standards and have a safety top or cap, if appropriate, unless written or noted exemption by the patient/prescriber is made.
- c. A customized patient package meeting USP standards for containing multiple drugs in time targeted packages should be discussed and offered to patients taking multiple medications.

**DP 0792. The prescription medication container shall be labeled in accordance with federal/state laws.**

### *Guidelines*

- a. Auxiliary label(s) should be used to clarify and/or emphasize the prescriber's instructions.
- b. Written drug use information should be considered (see Patient Counseling).

**DP 0892. The person responsible for handing the prescription medication to the patient or the patient's envoy shall be a pharmacist or a designee of the pharmacist.**

### *Guidelines*

- a. New Prescription - A new prescription should be dispensed personally by the pharmacist with appropriate counseling (see Patient Counseling).
- b. Refill Prescription - May be handed to the patient by ancillary personnel provided no changes have been made from the original prescription order and the pharmacist has ascertained that the patient is taking the drug appropriately, including handling of possible adverse effects and interactions due to subsequent changes in therapy.

**DP 0992. Ordinarily, prescriptions should be dispensed directly to the patient or the patient's envoy. In the event that, for matters of patient convenience, the pharmacist chooses to deliver the medication by alternative means (e.g. mail, delivery) it is the pharmacist's responsibility to the patient to communicate with the patient in a follow-up phone call to ascertain receipt of the medication and understanding of its use.**



Maryland Pharmacists Association  
650 West Lombard Street  
Baltimore, Maryland 21201-1572  
(410) 727-0746

# Recognizing Pharmacy Excellence

## *The 1993 MPhA Awards*

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the official Award Nomination Form on the back of this page. The Award Nomination Form information should be clear and legible. Forms should be sent to: **Award Nominations**, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation.

For consideration, all nominations **must** be received no later than March 31, 1993.

### *Seidman Distinguished Achievement Award*

**About the Award:** Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years.

**Who is Eligible:** Any MPhA pharmacist member who meets the criteria of the award.

### *MPhA Honorary President*

**About the Award:** An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time.

**Who is Eligible:** Any long standing contributor to the profession or the Association.

### *Wyeth-Ayerst Bowl of Hygeia Award*

**About this Award:** The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions.

**Who is Eligible:** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

### *Marion Merrell Dow Distinguished Young Pharmacist Award*

**About this Award:** Awarded to a pharmacist who has graduated within the past nine years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization.

**Who is Eligible:** Any MPhA pharmacist member who graduated from pharmacy school in 1984 or after.



Cutting to the heart of the pharmacist-patient relationship, 45 percent of those interviewed strongly agreed that "the pharmacist really cares about me and how I feel."

The survey also discovered a significant difference in patient compliance, depending on *who* in the pharmacy handed the finished medication to the patient. When the pharmacist, rather than a clerk, handed the medicine to the patient, noncompliance was reduced by 25 percent.

What reasons did patients offer for not following directions? Leading the list were: "I forgot....I took different amounts....I took it at different times." Mentioned less frequently were: "I only took it when I needed it....I was too busy to take it....The side effects bothered me."

But what about those patients who filled their prescription and took it either as directed or as they decided to on their own, did the medication help them? Ninety percent agreed that it did work while only six percent said it did not and four percent said they were not sure.

### **Non-Compliance = Non-Effective**

There is also an apparent link between taking the medication as directed and its effectiveness. Eighty-seven percent of patients who failed to take the proper dosage said the medication did not work. Sixty-six percent of patients who did not take medication at the proper times said it did not work, and 49 percent who neglected to take it for the full duration faulted the medication.

When patients are not fully satisfied with counseling, they are much more likely to say the medication failed to do what it was supposed to. Overall, six percent of those interviewed said the medicine failed against 16 percent who were dissatisfied with the pharmacy's instructions and 18 percent who were dissatisfied with the doctor's counsel.

### **What About Refills**

Examining the third facet of improper patient compliance -- not having prescriptions refilled -- two out of three patients (66 percent) recalled that their doctors told them whether or not the prescription should be

refilled. But the number of patients who received advice on refills from their pharmacists fell to only 18 percent.

What a missed opportunity to bring the patient back -- when the patient should be brought back to the pharmacy! Pharmacists might help patients remember to refill prescriptions by reminding them at about the time the initial prescription runs out. But only one in 20 patients (five percent) recalls getting such a reminder from their pharmacy.

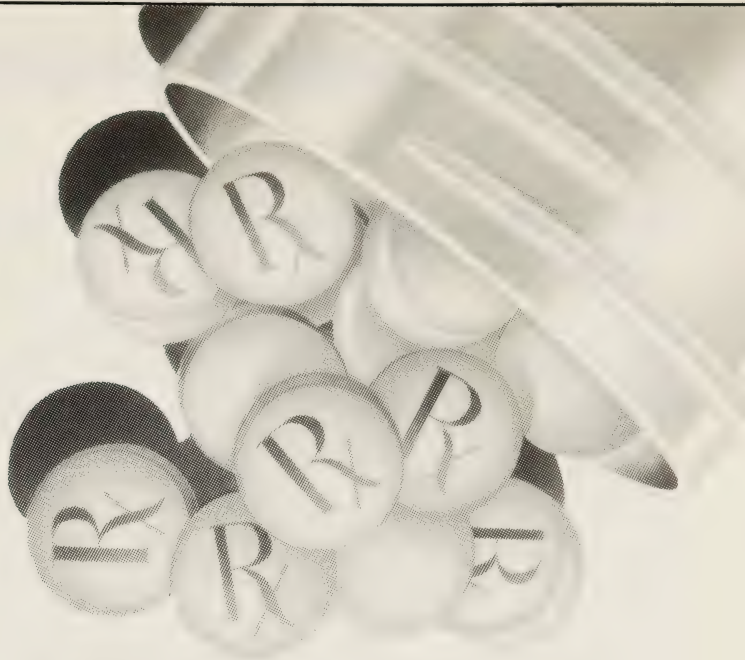
### **Conclusions**

Putting the findings into perspective, the survey reported the doctors got good scores on instructing patients on dosage, but slipped somewhat on possible side effects and interactions with other drugs or alcoholic beverages. Pharmacists most often failed to provide guidance to patients, and at an alarmingly higher rate than even five years ago.

Acknowledging that pharmacists are trained, dedicated and caring professionals who want to help patients get well -- and that good patient compliance is good pharmacy business -- it is clear that pharmacists should take an active role towards improving patient compliance.

The Schering Report urged pharmacists not to lose sight of their professional responsibility to use their "tools" diligently and consistently. Pharmacists must renew their commitment to help increase patient compliance and, thereby, in their own way, attack the nation's growing health care cost problem. It's not only good business, it's good medicine. **R**

A booklet summarizing the Schering study is available by writing: Pharmacy Affairs Department, Schering Laboratories, Kenilworth, N.J., 07033.



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(609) 848-3400



# Selecting the Best Product for Your Patient

## *A Brief Guide to the FDA Orange Book*

In 1980, the Food and Drug Administration first published what has now become known as *The Orange Book*. *The Orange Book* lists all drug products approved by the FDA as safe and effective and those products for which pharmaceutical manufacturers have received approval for production of generic drugs whose patents have expired. However, *The Orange Book* does not list those drugs marketed prior to 1938 (e.g., phenobarbital, digoxin) nor those drugs marketed between 1938 and 1962 which were approved for safety but are still under review for effectiveness.

This last category of drugs is most commonly known as DESI drugs (Drug Efficacy Study Implementation). DESI drugs may fall into three separate categories: drugs for which effectiveness have not been demonstrated, drugs that are currently undergoing efficacy studies, and drug which have not been shown to be effective but are similar to others that have demonstrated effectiveness. Therefore, the pharmacist needs to be aware that some older drugs may not appear in *The Orange Book* and may have a bioequivalence problem.

In 1992, the Maryland General Assembly passed legislation that eliminated the Maryland Formulary of Drug Products in favor of *The Orange Book*. Now, as soon as a product is listed as equivalent in *The Orange Book* it can legally be dispensed in Maryland. The only exceptions to this are six specific drug products that were exempted from substitution because of perceived problems with product equivalency. These products are: warfarin, phenytoin, valproic acid, primidone,

theophylline sustained released, and carbamazepine. The legislators also provided the Department of Health and Mental Hygiene with the ability to restrict substitution of other products if necessary.

Pharmacists using *The Orange Book* or the *USP/DI* which contains the FDA ratings to make their substitution decisions have pointed out how confusing the FDA rating system is. In short, if a drug product

is rated "A" the FDA considers it to be therapeutically equivalent to other pharmaceutically equivalent products. If a drug product is rated "B" the FDA has concluded that the products is not bioequivalent to other pharmaceutically equivalent products.

The table below is provided to help MPhA members make the best product selection decision possible for their patients.

R

Rating	Explanation
AA	Products in conventional dosage forms without bioequivalence problems
AN	Solutions and powders for aerosolization
AO	Injectable oil solutions
AP	Injectable aqueous solutions
AT	Topical products
AB	Products which had actual or potential bioequivalence problems and which are resolved by adequate testing of bioequivalence.
BC	Extended release dosage forms (tablets, capsules, injectables)
BD	Active ingredients and dosage forms with actual problems
BE	Delayed release oral dosage forms
BN	Products in aerosol-nebulizer drug delivery systems
BP	Active ingredients and dosage forms with potential problems
BR	Suppositories or enemas for systemic use
BS	Products which have drug standard deficiencies
BT	Topical products
BX	Products for which there is insufficient information to determine equivalence.

# Restoring Vitality in Community Pharmacy

*Bruce R. Siecker, Ph.D., R.Ph., Executive Vice President, NWDA*

If "confusion is the moment of chaos between what is no longer and what is not yet," then it is easy to say that community pharmacy is in a confused state. Gross margins, especially in the professional services area, continue to slide, while front end business increasingly migrates to super discount outlets and warehouse clubs.

Buying profits that result from anticipating manufacturers' price increases have fallen precipitously in the past year, while a variety of new practice requirements mandated for Medicaid (and hence everyone else) recipients can be expected to drive costs up while cutting professional productivity. And if that's not enough, the new administration in Washington, D.C. claims to have earmarked the entire industry-profession for "special attention" as part of so-called health-care reform.

Faced with all these challenges, it is easy for pharmacy managers to get discouraged and to settle into a parochial morass that sees all of this happening only to community pharmacies ... or, only to me. Nothing could be farther from the truth.

## Change is Endemic

Change is everywhere and it is affecting all parts of the economy, all areas of the country, and all aspects of the health-care delivery system. The legendary boxer, Joe Louis, allegedly said to an opponent, "You can run, but you cannot hide." When it comes to change and its effect on community pharmacy, however, it is more useful to extend this pugilistic epigram to say that, "You can hide, but you cannot escape."

It doesn't matter whether an enterprise is a \$1 million per year independent community pharmacy or a multi-billion dollar giant; there is no escape. Everyone may not experience change at the same time, but it will happen to everyone. Seemingly impervious giants as IBM, General Motors, McDonnell-Douglas, and American Express are being battered by change that they did not even create (though some would say that their problems are a result of not reacting quickly or boldly enough to change). American Express got rich in the 1980s; however, value-conscious consumers are looking elsewhere and being wooed by a legion of credit-card competitors offering better deals, discounts, and rebates. As a result, American Express has been losing 500,000 credit-card customers *per fiscal quarter* for the past nine months.

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*Change is everywhere and it affects all parts of the economy, all areas of the country, and all aspects of the health care delivery system.*

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IBM makes too many mainframe computers that too few businesses want anymore. General Motors has the highest costs of any major auto maker and few state-of-the-art products. The end of the Cold War and an abrupt downturn in orders by commercial airlines (down 58 percent), is hammering airplane giant McDonnell-Douglas so badly that it may get out of the business completely.

## Problems Closer to Home

Drug manufacturers and drug wholesalers are fighting margin erosion too, and chain drug store sales were up only seven percent in 1992 (over 1991). A key concern among chain drug stores is the continuous decline in gross margins in the prescription departments as third-party programs continue to grow. Price increases, long the salve that buffered drug manufacturers (and drug wholesalers to a somewhat lesser extent) from the foibles of drug research and development, a growing over-capacity in the distribution channel, and a recessionary economy, have slowed dramatically. According to the NACDS PRIME Index, the inflation in drug prices was only five percent (on an annualized basis) in the third quarter of 1992 for those drugs that experienced a price increase. The overall increase was even less, and there is little if any indication that the rate will change in the near term.

Most pharmacists can remember when gross margins for prescription services were 15-20 percentage points above what they are today. A cursory examination of the aggregate gross margins of most third-party prescriptions, and a surprising number of self-pay transactions, shows margins in the mid to low twenties, i.e., somewhere between 21-24 percent gross margin. While pharmacy operators are rightfully alarmed by such numbers, and probably have reason to be concerned that the slide has not ended, few appear to be doing much of anything about it. Some chain drug stores report efforts to look at operations



with the aim of cutting operating costs, but very, very few have designed pharmacies that can survive (and even produce profits) on margins in the 18-22 percent range.

Aggressive counter measures designed to deal with falling margins as though they are irreversible are modest at best. Most pharmacy managers appear to favor tactics designed to restore margins of yesteryear or at least to ride out the current dip which is seen as temporary. Both views are doomed to fail, because pharmacy margin -- prescription and front end -- are not going to rebound! If anything, they are headed still lower. Anyone who fails to grasp that a sea lane change in margins has occurred, and that it is never again going to be like it once was, is doomed to go down with their good ship pharmacy.

#### A Shift in Consumer Behavior

Everyone knows that third-party drug programs are aggressive price shoppers. (Some would be more graphic in describing their purchasing behavior.) The same is partially true for individual consumers. Some are price shoppers; others value convenience or service or quality or ambiance above price. While it is dangerous even to believe that all consumers think and act alike about all goods and services, there is substantial evidence to suggest that a major proportion of consumers today have shifted strongly toward low price as their primary focus.

According to Tactical Retail Solutions, a New York-based retail analyst, there has been a massive shift

#### *Retailer and Consumer Rankings*

	<b>Retailer Perceptions</b>	<b>Consumer Actions</b>
Emphasis on quality service	24.1%	3.4%
Promotions/markdowns	22.0	16.3
Better quality products	16.0	8.9
Everyday low prices	10.4	22.7
Larger selection	10.0	17.2
More exclusive products	8.8	5.1
Convenient location	8.6	16.5

in shopping thinking and habits in the past several years and the shift is continuing. In short, today's consumer will forego fancy, flashy, and fluff for a cheaper price. Discounters, outlet malls, warehouse clubs, and mail order firms are positioned very well to take advantage of "saving above all else mentality," and indeed proved the thesis by achieving record sales again during this year's holiday season.

The continuing recession and changing demographics have contributed to a major shift in focus in only two years. Even upscale shoppers in upscale communities are now "cross shopping" in stores they would never have been seen in only a few years ago. A recent study by Deloitte & Touche demonstrates a gap between those who sell and those who buy. Retailers were asked what they believed shoppers looked for, while shoppers were asked what they are looking for today. The results are illuminating and appear in the table on this page.

No one claims that low price is the only factor that accounts for buying

behavior, that shoppers motivations are the same for all goods and services (or in all communities in all parts of the country). But, it is perilous to believe that pharmacy shoppers are not price conscious and that pharmacy is immune to fundamental shifts in the broader retail or societal contexts.

#### Meanings For Community Pharmacy

There is nothing written anywhere that guarantees the U.S. system of delivering prescription and non-prescription medicines and health and beauty aids. Community pharmacies exist because they serve a vital purpose and because enough consumers use their services to maintain the system. That's all! A continuing existence is predicated on serving the public's needs in the way it wants to be served *and* in producing a return sufficient to attract human and financial capital in the long run.

In spite of massive changes, falling margins, shifts in shopping behavior, and a dozen other challenges,

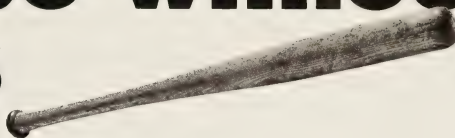
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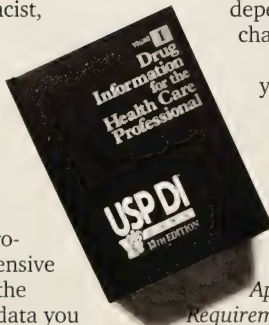


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community pharmacy continues to hold its own. Some are even prospering; a few are clear winners (today at least). Most, however, could be doing much better. The key to restoring vitality to community pharmacy resides in a paraphrasing of a popular Lee Iaccoca-ism, "In the pharmacy business, you lead, follow, or get out of the way."

The first steps in restoring financial vitality to community pharmacy is acceptance and recognition of several "givens," which include:

- Change affects everyone and anything. Surviving means seeing and reacting to change *before* it adversely affects a pharmacy.

- A pharmacy needs to be as customer driven as possible. That means staying in tune with what consumers want today and tomorrow. Shopping habits have changes and will change in the future and so must pharmacy.

- There are no guarantees. A pharmacy exists only so long as it fulfills needs and is profitable.

- What worked yesterday may not work today and probably won't work in the future. If a pharmacy is not dynamic -- growing and changing continuously -- it's static. A static organism isn't growing and adapting; it's dying.

- Answers cannot be found in the past. Efforts designed to restore "what was" yesterday are better used to address "what is" today.

The American marketplace plays no favorites. It takes continuous re-invention to stay ahead, and re-invention is hard work. The alternative is to wither slowly away as the world beats a path to more attractive alternatives. Fortunately, there are solutions if they are sought and community pharmacists have always come up with solutions. The time to start is now because the clock is ticking.

R

## Pharmacy Update

*Leon Weiner, P.D.*

### The following are newly licensed pharmacies in Maryland:

White Shield Pharmacy #151  
231 Tippin Drive  
Thurmont, MD 21788 (10/92)

Safeway Pharmacy #1129  
10276 S. Maryland Blvd.  
Dunkirk, MD 20754 (10/92)

F&M Pharmacy #107  
242 W. 29th St.  
Baltimore, MD 21218 (10/92)

Wal-Mart Pharmacy 10-1867  
280 Woodward Road  
Westminster, MD 21157 (10/92)

Peoples Drug #1879  
11800 Rockville Pike  
Rockville, MD 20852 (10/92)

Thrift Drug #8645  
1321 Riverside Pkwy.  
Belcamp, MD 21017 (10/92)

Giant Pharmacy #1215  
7546 Annapolis Road  
Lanham, MD 20785 (10/92)

Rite Aid #3217  
5421 Reisterstown Rd.  
Baltimore, MD 21215 (10/92)

Peoples Pharmacy #1881  
Dunkirk Marketplace, Rte. 4  
Dunkirk, MD 20754 (11/92)

Twin Knolls Pharmacy  
10 Hillcrest Plaza  
Frederick, MD 21702 (11/92)

Revco Discount Drug #2650  
1580 Wesel Blvd.  
Hagerstown, MD 21740 (11/92)

### Two pharmacies have new locations:

Prescription Care, Inc.  
6480 Dobbin Road, Ste. A  
Columbia, MD 21045 (10/92)  
(formerly at 8980 Route 108)

Medicine Shoppe #16  
901 Eastern Avenue, Suite 100  
Essex, MD 21221 (10/92)  
(formerly at 325 S. Marlyn Avenue)

### There are five new infusion pharmacies in Maryland:

Pharmacy at Whitemarsh  
8321 Belair Road  
Baltimore, MD 21236 (10/92)

Home Intensive Care  
513 Commerce Drive  
Upper Marlboro, MD 20772 (11/92)

Ingleside Pharmacy  
325 Hospital Dr., Ste. 204  
Glen Burnie, MD 21061 (11/92)

Curaflex Infusion Services  
10200 Old Columbia Rd., Stes.  
M&N  
Columbia, MD 21046 (11/92)

I<sup>2</sup> Home Therapeutics, Inc.  
2141 Industrial Parkway, Ste. 109  
Silver Spring, MD 20904 (11/92)

### Two pharmacies have closed:

I.D.R. Lab & Clinic Ltd.  
14915 Broschart Road  
Rockville, MD 20850 (11/92)

Critical Care America  
9130A Guilford Road  
Columbia, MD 21046 (11/92)

R

# Insurance Covers Negligence and Sloppiness

David B. Brushwood, J.D.



A patient sued a Florida pharmacy to recover for damages allegedly caused by the pharmacy. The pharmacy's insurance company defended the legal action on behalf of the pharmacist, but after two years of litigation, the insurance company became insolvent and a state insurance fund took over the defense. The case was settled for \$300,000 against the pharmacy.

The state insurance fund contended that there was no duty for it to defend the pharmacy, or provide malpractice insurance coverage, because there was a clause in the initial policy of insurance that excluded coverage for the "willful violation of a penal statute."

So-called "illegal acts" clauses in pharmacist malpractice insurance policies have for many years caused concern for pharmacists. Just about everything a pharmacist might do to harm a patient (dispense the wrong drug, place the wrong directions for use on the label, etc.) could be considered an illegal act, and could also be a violation of a penal statute. But if the insurance company is going to deny coverage any time there is a claim, then of what use is the insurance?

In this Florida case, the court recognized that the pharmacist ran his pharmacy negligently and sloppily. However, this conduct was held not to rise to the level of willfulness. Only those illegal acts that are intentionally done, rather than those that are inadvertently done, are excluded from insurance coverage. Therefore, the court concluded that there was coverage under the policy, and that the state insurance fund, standing in the shoes of the insolvent insurance company, had a duty to defend the pharmacist. This ruling is consistent with prior analogous cases, and should provide comfort to pharmacists who are concerned about the scope of their malpractice insurance coverage. **R**

Based on: *Florida Insurance Guaranty Association v. Ali*, 1992 Westlaw 296129 (October 20, 1992)

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# Continuing Education

## Continuing Education Quiz

January 1993 -- Professionalism

This month's questions are taken from the articles in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by June 30, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

Is this program used to meet your mandatory CE requirements? ☐ Yes ☐ No

Was this issue/article useful to you in your practice? ☐ Yes ☐ No

1. What percent of Americans have seen a physician within the past year?
  - a. 25 percent
  - b. 52 percent
  - c. 79 percent
  - d. 97 percent
2. The most common reason for visiting a physician is:
  - a. onset of a new health problem
  - b. routine physical
  - c. chronic condition follow-up
  - d. resolving medical claim
3. Missed prescription refills cost pharmacies an average of \_\_\_\_\_ per pharmacy per year.
  - a. \$ 5,000
  - b. \$ 10,000
  - c. \$ 20,000
  - d. \$ 50,000
4. MPhA's *Principles and Guidelines for Pharmacy Practice in Maryland* are:
  - a. voluntary suggestions
  - b. legal requirements
  - c. mandatory for belonging to MPhA
5. In most cases, to determine if a drug product is bioequivalent, a Maryland pharmacist should refer to:
  - a. The Maryland State Formulary
  - b. The FDA Orange Book
  - c. Facts and Comparisons
  - d. Pharmacy Laws and Regulations for Maryland
6. The generic version of Hultra is rated "BD." A pharmacist may:
  - a. substitute this drug for Hultra
  - b. may not substitute this drug for Hultra
  - c. call the physician for a new prescription or authorization to dispense the generic version
  - d. b or c
7. What area did retailers believe consumers wanted most in a recent survey?
  - a. everyday low prices
  - b. better quality products
  - c. promotions and markdowns
  - d. emphasis on quality service
8. In reality, what did consumers think was most important:
  - a. everyday low prices
  - b. better quality products
  - c. promotions and markdowns
  - d. emphasis on quality service
9. In *Florida Insurance Guaranty Association v. Ali*, the court ruled that:
  - a. insurance coverage includes negligence
  - b. insurance coverage includes sloppiness
  - c. insurance does not cover willful negligence
  - d. all of the above



**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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**PHARMACY FOR SALE** This is your opportunity to own a profitable established pharmacy in a friendly waterfront town in MD. Sales volume of \$1,300,000. Prescriptions filled annually 29,500. For further information, call or write Myers & Hill Realtors, One Mill Place, Suite 203, Easton, MD 21601. Phone (410) 822-0664.

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## Want to Place An Ad?

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* and reach 1,400 other pharmacists for free.

Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50.

To place an ad, send your typewritten copy to MPhA, 650 West Lombard Street, Baltimore, MD 21201-1572. Or you can FAX your ad to (410) 727-2253.

**RXCOLLECTIBLES** Pharmacist selling Large Brass Bukelew and Waterman Balance, Philadelphia, 19th Century with weights -- \$500. 13 Mortar/Pestles, brass, 19th Century -- \$1,850. 3 Mortar/Pestles, wood, 19th Century -- \$300. 14 Pharmaceutical bottles, 19th and 20th Century, 4 extra tops with ground glass -- \$700. Boxed weight set, 19th century -- \$100. Weight set, bronze, 19th century -- \$90. Call (410) 745-5485 or write PO Box 984, St. Michaels, MD 21663.

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**FOR RENT** Ocean City, 122nd St. Luxurious townhouse with 25 foot oceanfront decks, 3 levels, 4 bedrooms, sleeps 10 all extras. Families only. Available week of MPhA Convention, \$1250/week. Also weeks in July and August, \$1500/week. Weeks in September, \$1250/week. Call Joel at (301) 652-8289.

**CE & SKI WEEKEND** Enjoy the Mid-Atlantic's best skiing at Snowshoe/Silver Creek Resort, WV. Earn 6 hours ACPE approved CE on Patient Counseling, March 12-14, 1993. Call or write PharmaServ, 209 Wayne Avenue, Elkins, WV 26241, (304) 636-4314.

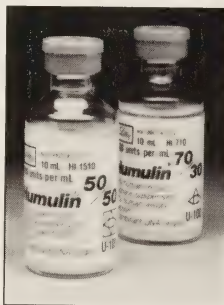
**OTC HANDBOOKS AVAILABLE** The ASP Chapter of UMAB School of Pharmacy has a limited number of copies of the ninth edition of *The Handbook of Nonprescription Drugs*. This book is a must for practitioners. Cost is only \$78, a \$30 savings off the listed price. Get your copy now by calling Abigail Lagman at (410) 244-0965. Best time to call is in the evening, but if no answer, please leave a message.



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New Humulin 50/50 is the tailor-made answer to individual patient needs. A unique combination of equal amounts of Regular human insulin and NPH human insulin, it will be useful in situations in which a greater initial insulin response is desirable for greater glycemic control.

Like Humulin 70/30\*, new Humulin 50/50 offers the convenience and accuracy of a premix. And it can be used in conjunction with an existing 70/30 regimen.



### New **Humulin** <sup>50</sup>/<sub>50</sub>

50% human insulin  
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#### *The Newest Option in Insulin Therapy*

**WARNING:** Any change of insulin should be made cautiously and only under medical supervision.

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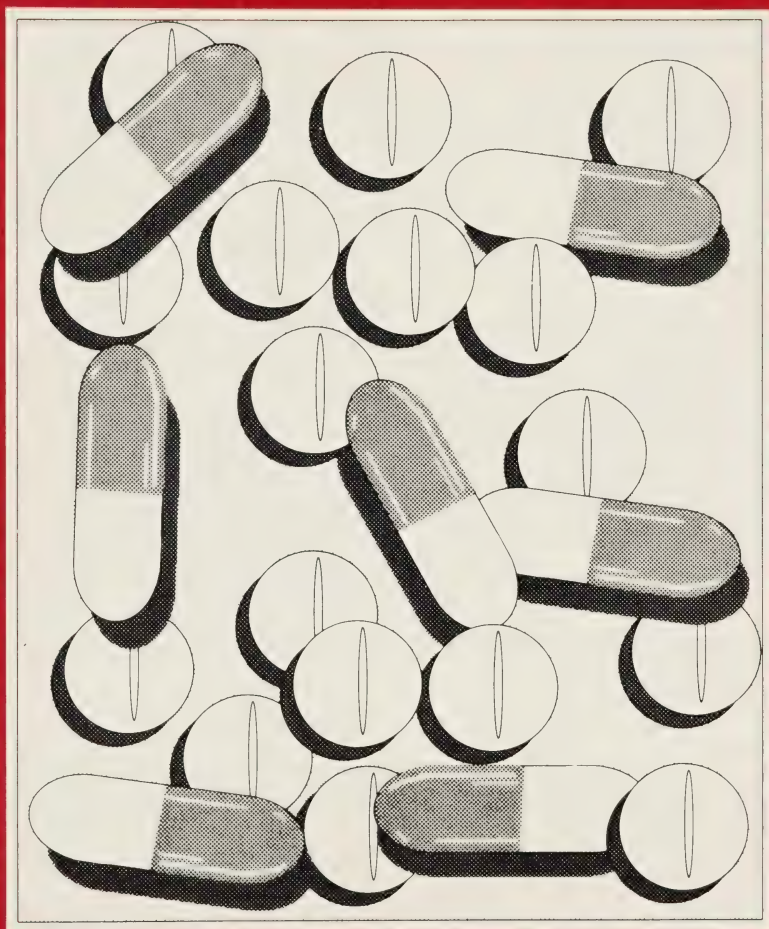
Global Excellence in Diabetes Care  
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46285

# *The Maryland Pharmacist*

VOL. 69

FEBRUARY, 1993

NO. 2



*A Review of the New Drugs*





## Pharmacists Working Together for Tomorrow

The Maryland Pharmacists Association  
1993 Mid-Year Seminar

Sunday, February 21, 1993  
Loews Annapolis Hotel, Annapolis

### Program

- 8:00 am Continental Breakfast  
Registration
- 8:45 am Presidential Welcome  
Nicholas Lykos, P.D.
- 9:00 am *Continuing Education Seminar*  
**New Drug Update for 1993**  
David S. Roffman, Pharm.D.  
Robert A. Kerr, Pharm.D.  
University of Maryland  
School of Pharmacy
- 12:30 pm Luncheon
- 1:30 pm MPhA House of Delegates Meeting  
Ernest Testerman, P.D., presiding
- 2:00 pm *Continuing Education Seminar*  
**Pharmaceutical Care within National  
Health Care Reform**  
John A. Gans, Pharm.D.  
Executive Vice President  
American Pharmaceutical Association

### Registration

Registration is \$40 for MPhA Members (\$50 for non-members) if registration is postmarked by February 14, 1993. Registration postmarked after February 14, 1993 and on-site will be (\$50 for members (\$60 for non-members).

To register for the Mid-Year Seminar, complete and detach the accompanying registration form. Return the form with payment (check or money order) to the MPhA office. For further information or questions, contact MPhA at (410) 727-0746 or (800) 833-7587.

Cancellation refunds will be made upon request, minus a \$5.00 handling charge, if registration is canceled at least 72 hours before the seminar. All refunds will be processed after the seminar.

### Directions

The Loews Annapolis Hotel is located at 126 West Street in Annapolis. MPhA Mid-Year Seminar attendees get *free* valet parking at the Hotel. From Baltimore: From I-695 take I-97 south to the merge onto Route 50 East. Take the Route 70/Rowe Boulevard exit into Annapolis. Bear right and proceed through two lights to West Street. Turn right onto West Street. The Loews Annapolis Hotel is about one block north on the right hand side. From Washington: From I-95, take Route 50 East to Annapolis. Take the Route 70/Rowe Boulevard exit into Annapolis. Follow directions above. A map is available from the MPhA office.

### 1993 MPhA Mid-Year Seminar

February 21, 1993

Loews Annapolis Hotel

\$40.00 MPhA Members

\$50.00 Non-Members

(before February 14, 1993)

YES! Please register me for the February 21, 1993 MPhA Mid-Year Seminar. I am enclosing a check in the amount of \$40.00 (\$50 for non-members) for my advance registration.

Name \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIPcode \_\_\_\_\_

Return Registration Form with payments to:

**MPhA Mid-Year Seminar Registration**

650 West Lombard Street, Baltimore, Maryland 21201-1572

# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

February 1993

Volume 69

Number 2

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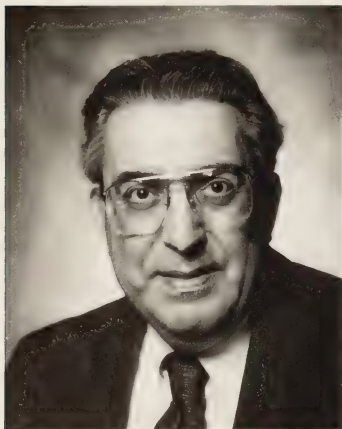
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## President's Commentary

Nicholas C. Lykos, P.D., President



For many years, pharmacy at the local and regional level have looked to our national organizations for leadership and direction. For as many years that I can remember, pharmacy has been in the reactive role of all and any decisions that affect our profession. But that has changed now. Both NARD and APhA, the two largest practitioner organizations, have released position papers on national health care reform.

NARD should be applauded for presenting their call prior to the inauguration of President Clinton. As president of your Association, I have asked both our Legislative and Professional Issues Committee to study these proposals and decide whether MPhA should endorse their recommendations.

The issue of some form of universal health insurance and assurance for Americans is a major topic for the executive and legislative branches of both our federal and state governments. The Library of Congress' Congressional Research Service (CRS) recently prepared a major planning document on health insurance for our national representatives.

I thought you might be interested in some of the CRS findings. Their report points out that nearly 35 million of the American population is uninsured and generally are the young (under age 24). the uninsured are poor; most have ties to small firms with seasonal and temporary employment. The rising cost of health care over the past ten years grew faster than our economy. The United States spends more per capita and a greater proportion of its gross domestic product on medical care than any other nation. One of every seven dollars is expended for health care in the U.S. These are all sobering statistics for us as pharmacists, as consumers, and as taxpayers.

The preface to NARD's health care reform position paper notes that more than 30 legislative proposals were introduced in the last Congress to address our nation's health care problem. The presenter of the various proposals represented the cream of our most health savvy legislators including: Waxman, Rostenkowski, Stark, Cohen, Durenberger, Rockefeller, Dole, and others. Even Maryland's own Ben Cardin is actively involved in promoting a more rationale approach to health care access and delivery.

However, even with some many options, nothing of any major effects was resolved.

What's the story with pharmacy in this huge health system? According to HCFA the expenditure of drugs has grown from \$9 billion in 1970 to \$21 billion in 1980. The last year's figures available were from 1990 -- the cost? Nearly \$55 billion. But, the most striking fact is that the expenses of drugs as a proportion to total health care expenditures has actually dropped. Pharmacy's share of the health care pie went from 12 percent in 1970 to 8.6 percent in 1980 and down to 8.2 percent in 1990. 1970-12%, to 8.6% in 1980 and 8.2% in 1990.

During that some period, the cost for pharmacy services per capita has increased from \$41 in 1970, to \$92 in 1980 and \$210 in 1990. The 1990 annual rate of increase in drug prices is now about eight and one-half percent, down from the peak of 10 percent in 1985 and comparable to the

*Concluded on page 18....*



## A Review of 1992's New Drugs

Thomas A. Gossel, R.Ph., Ph.D., Ohio Northern University  
J. Richard Wuest, R.Ph., Pharm.D., University of Cincinnati



This special review of the new drugs introduced into the U.S. marketplace in 1992 is provided to you through a joint effort of the Maryland Pharmacists Association, the State Pharmaceutical Editorial Association, and the generous educational support of Searle. MPhA members can earn up to five continuing education credits for only \$ 5.00 (non-members pay \$50.00) by completing the special tear-out continuing education quiz beginning on page 15 of this issue. To qualify for credit, all quizzes must be completed and submitted to the MPhA offices by September 30, 1993.

### ACE Inhibitors



There are four new angiotensin converting enzyme (ACE) inhibitors: **benazepril** (Lotensin--Ciba-Geigy), **fosinopril** (Monopril--Bristol-Myers Squibb, Boehringer Ingleheim), **quinapril** (Accupril--Parke Davis), and **ramipril** (Altace--Hoechst-Roussel, Upjohn)

ACE inhibitors exert their antihypertensive effects by lessening the formation of angiotensin II, a potent vasoconstrictor. Hemostasis is maintained by several mechanisms which adjust to periods when blood flow must be shifted from one area to another. For example, in the "fight or flight" phenomenon, blood must be shunted from the skin and subcutaneous areas to muscles so that the person can respond appropriately. Other times, such as during sleep, a relatively low blood pressure is required.

Angiotensin converting enzyme plays a major role in blood pressure regulation. Briefly, the inactive peptide angiotensinogen is metabolized to angiotensin I by the enzyme renin. Angiotensin I is then converted by ACE to angiotensin II. Angiotensin II is a potent vasoconstrictor, and also stimulates the adrenals to release aldosterone. This mineralocorticoid increases sodium and water retention to raise blood pressure further.

ACE also catalyzes conversion of bradykinin, the vasodilator counterpart to angiotensin II, to inactive peptides. Normally, bradykinin and angiotensin II are produced as needed to maintain proper blood pressure. Since the enzyme is the catalyst to increase angiotensin II and decrease bradykinin, it can be seen that a drug which inhibits it will reduce elevated blood pressure.

ACE inhibitors also influence the body's fluid levels. By inhibiting angiotensin II production, they reduce aldosterone release. Thus, less sodium is retained, more water is excreted, and total body fluids are reduced.

ACE inhibitors act upon the renin-angiotensin-aldosterone system beyond the site of renin influence. Therefore, unlike thiazides and beta-adrenergic blockers, ACE inhibitors lower elevated blood pressure regardless of renin levels. This increases the range of patients for whom they are effective.

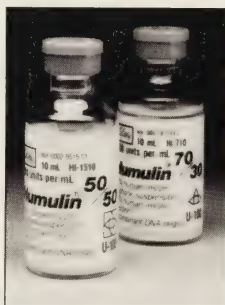
The new drugs, like their predecessor enalapril, are prodrugs that are converted to active metabolites following oral administration. As with lisinopril, all four can be administered



## Because One Size Doesn't Fit All...

New Humulin 50/50 is the tailor-made answer to individual patient needs. A unique combination of equal amounts of Regular human insulin and NPH human insulin, it will be useful in situations in which a greater initial insulin response is desirable for greater glycemic control.

Like Humulin 70/30\*, new Humulin 50/50 offers the convenience and accuracy of a premix. And it can be used in conjunction with an existing 70/30 regimen.



### New **Humulin** 50/50

50% human insulin  
isophane suspension  
50% human insulin injection  
(recombinant DNA origin)

#### *The Newest Option in Insulin Therapy*

**WARNING:** Any change of insulin should be made cautiously and only under medical supervision.

\* Humulin® 70/30 (70% human insulin isophane suspension, 30% human insulin injection [recombinant DNA origin]).



Global Excellence in Diabetes Care  
**Eli Lilly and Company**  
Indianapolis, Indiana  
46285

**TABLE 1**  
**Comparison of New ACE-inhibitor Drugs**

Generic Name	Trade Name (Mfr)	Availability	Active Metabolite	Frequency of Dosing
Benazepril	Lotensin (Ciba-Geigy)	5, 10, 20 & 40 mg tablets	Benazeprilat	1-2 x/day
Fosinopril	Monopril (Bristol-Myers Squibb; Boehringer Ingelheim)	10 & 20 mg tablets	Fosinoprilat	once daily
Quinapril	Accupril (Parke-Davis)	5, 10, 20 & 40 mg tablets	Quinaprilat	1-2 x/day
Ramipril	Altace (Hoechst-Roussel; Upjohn)	1.25, 2.5, 5 & 10 mg capsules	Ramiprilat	1-2 x/day

on a once- or twice-daily dosage regimen.

Adverse reactions most commonly reported include nausea, headache, dizziness, fatigue, and a dry, nonproductive cough. Postural (orthostatic) hypotension, although rare, is reason to advise patients that lightheadedness may occur, especially during the first several days of therapy. The drugs can elevate serum potassium. Individuals with diabetes or renal insufficiency, and those taking a potassium-sparing diuretic (e.g., amiloride, spironolactone, triamterene) are at special risk. Concomitant use of these agents and an ACE inhibitor should be avoided. All products have this warning in their labeling and some contraindicate concomitant use. The same is true for potassium supplements.

Recently, FDA told manufacturers to strengthen the warning that the use of ACE inhibitors by pregnant women should be avoided, and to make it a part of a "boxed warning." The drugs can cause fetal and neonatal morbidity and mortality. Problems include skull hypoplasia, neonatal hypertension, renal failure, and death. Unlike other teratogenic birth defects which occur during the first trimester, the problem with ACE inhibitors is critical in the second and third trimesters of pregnancy.

ACE inhibitors can be taken without regard to food. It is best that each dose always be taken with food or always on an empty stomach. Doses should be taken at the same time each day. In the event that a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The manufacturer of Monopril states that antacids may reduce absorption, thus lowering serum concentrations. If concomitant therapy is necessary, dosing should be separated by two hours. ACE inhibitors can cause potassium retention. Salt substitutes should be avoided unless ordered by a physician.

ACE inhibitors can cause angioedema, especially following the first dose and in the facial area. Before taking further doses, patients should inform the physician of signs of angioedema such as swelling of the face, lips, tongue, or eyes, or difficult breathing. Other symptoms that should be reported to the physician are persistent sore throat or fever (signs of neutropenia). Women who become pregnant while taking an ACE inhibitor should consult their physician promptly.

## Calcium Channel Blockers

Felodipine (Plendil--Merck Sharp & Dohme) is a new calcium channel blocker (CCB) for treatment of essential hypertension. It shares the same mechanism of action for reducing blood pressure as that of other calcium channel blockers.

To explain briefly, smooth muscle cell membranes are comprised of layers of lipid interspaced with protein and carbohydrates. Cell membranes are impervious, thus maintaining osmotic integrity. Water, ions and other materials enter and leave cells by special transport systems including a system of channels. In their resting state, the cell membrane, being lipophilic and hydrophobic, repels water-soluble ions. When smooth muscle cells depolarize, i.e., receive an electrical impulse from neurons, the ionic charge on the outside of the membrane changes. This allows specific ions to pass through their channels into the cells.

Two important ions for muscle contraction are sodium and calcium. Sodium ions are smaller so they can enter more quickly. Though the time difference is extremely short, the systems are referred to as the "fast" (sodium) channel and the "slow" (calcium) channel. The result of calcium entry is contraction.

It is believed that sodium channels provide an immediate electrical impulse to cells to insure a high reliability for contraction. This primes muscle fibers to start the contractile process, assuring that a complete electrical impulse has been received and that conduction and contraction will occur. CCBs retard calcium influx into the cells.

Their mechanism is further explained in that within smooth muscle cells, calcium ions play an integral role in causing contraction. Within the sarcoplasmic reticulum, calcium combines with an endogenous substance (calmodulin in blood vessels;



troponin in myocardial tissue). This combination, in turn, attracts the proteins actin and myosin which, in their resting state, are separated, to slide over each other. With this action, the physical size of the cell decreases, resulting in muscle contractions. So, lessening the influx of calcium ions into smooth muscle cells, e.g., arteries, reduces their contraction.

Felodipine is a member of the dihydropyridine group of CCBs. Others include isradipine (DynaCirc), nifedipine (Cardene), nifedipine (Procardia, etc.) and nimodipine (Nimotop). These agents can cause reflex tachycardia during initiation of therapy. The other CCBs verapamil (Calan, Isoptin, etc.) incite little or no change in heart rate, but can slow atrioventricular (AV) conduction. Therefore, these two drugs can interact with beta-adrenergic blockers. The dihydropyridines do not slow AV conduction and may be safer for use with beta-adrenergic blockers. All CCBs should be used with caution, if at all, in persons with heart failure.

Felodipine is well tolerated in most patients. Adverse effects include peripheral edema (most common), headache, flushing, tachycardia, palpitations, and postural dizziness. All are related to the drug's vasodilation action. Gingival hyperplasia (overgrowth of gum tissue) has also been reported. CCBs as a group are not likely to increase serum lipid levels like some other antihypertensives such as the thiazides.

Plendil is marketed in 5 mg and 10 mg controlled-release tablets and is taken once daily. The drug is interspersed with hydrophilic agents that hydrate, swell, and dissipate, to release active ingredients. Patients should be advised to swallow the tablets whole; crushing or chewing destroys the controlled-release property.

Although it can be taken with meals, the best time to take Plendil is on an empty stomach with a full glass of water. Doses should be taken at the same time each day. In the event

a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The following signs and symptoms should be reported to the physician if they occur: headache, nausea, swelling of the extremities, unusually slow heartbeat, chest pain, unusual tiredness or difficult breathing.

---

### *Antithrombotic*

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**Ticlopidine (Ticlid--Syntex).** This antithrombotic is indicated for reducing the risk of thrombotic stroke in patients who have experienced stroke precursors, and in those who have had a completed thrombotic stroke. Because there is a risk of life-threatening neutropenia and agranulocytosis, ticlopidine should be reserved for patients who are intolerant to aspirin.

While the exact mechanism of action of ticlopidine is not fully known, it does act differently than aspirin or dipyridamole, the other antiplatelet agents. Formation of a blood clot consists of the aggregation, adhesion, lysis and deposition of platelets to form a hemostatic plug. During this sequence of events, platelets congregate, stick together, break apart and release a number of substances that will catalyze the eventual formation of the permanent clot.

Patients with thromboembolic disorders experience this too often. Preventing platelets from aggregating excessively reduces clot (thrombus) formation. This, in turn, reduces the breaking away of clots (emboli) from their point of formation. Emboli circulate to small blood vessels where they can lodge and block blood flow to the area. If this occurs in the heart, the result is a myocardial infarction; in the brain, a thrombotic stroke.

Aspirin exerts antiplatelet action by acetylating, thereby inhibiting the enzyme cyclooxygenase. This lessens formation of thromboxane  $A_2$ , a

prostaglandin derivative that induces platelet aggregation. Dipyridamole has several activities including inhibition of the enzyme phosphodiesterase. This increases platelet cyclic-AMP levels which stabilizes and renders them less likely to adhere to each other.

Ticlopidine does not affect either enzyme. Rather, it appears to interfere with the ability of platelets to adhere to each other. The net result is inhibition of platelet aggregation. It may also impair platelet adhesion and deposition on previously formed atherosclerotic plaque. A slight inhibition of platelet aggregation is noted in six hours. Maximum therapeutic effect can be achieved after three to five days of oral therapy.

The results of two large trials with ticlopidine attest to its activity. The Canadian American Ticlopidine Study (CATS) and Ticlopidine Aspirin Stroke Study (TASS) collectively evaluated more than 4,000 patients. In people who had experience a recent stroke, the incidence of a second stroke, myocardial infarction or vascular death was reduced 30 percent compared to placebo. It was significantly better than aspirin in preventing death from all causes of nonfatal stroke. Moreover, ticlopidine appears to be equally effective in both men and women.

There are two important considerations when counseling patients taking Ticlid. First, ticlopidine can cause intense irritation to the gastric mucosa resulting in ulceration and bleeding. The drug, must, therefore be taken with food.

Second, ticlopidine cause neutropenia in 2.4 percent of patients in clinical trials. FDA requires a boxed warning in its package insert stating that it is essential for complete blood counts and white blood cell differentials to be performed every two weeks beginning the second week of therapy through the third month. This corresponds to the period of greatest susceptibility of ticlopidine-induced neutropenia. The manufacturer

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assures that the blood work is free to patients; the physician must order the tests, however.

Ticlid is marketed as 250 mg tablets. It should be taken twice daily.

### *Antihypercholesterolemics*

**Pravastatin** (Pravachol--Bristol-Myers Squibb) and **Simvastatin** (Zocor--Merck Sharp & Dohme). These new drugs join lovastatin (Mevacor) and are indicated as adjuncts to diet for reduction of cholesterol in patients with primary hypercholesterolemia (Types IIa and IIb). More than 1,000,000 patients to date have been successfully treated with lovastatin, prompting development of the two new drugs. Other similar drugs will undoubtedly join the group in the future.

Both new drugs, like lovastatin, inhibit 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase in the liver. This enzyme catalyzes the rate-limiting step in cholesterol biosynthesis conversion of HMG-CoA to mevalonate. This step in cholesterol synthesis with drugs resulted in blockade at sites further along the path. A previously marketed drug, triparanol (MER-29), caused accumulation of intermediate metabolites and, eventually, toxicity. The HMG-CoA reductase inhibitors do not do this. They reduce total cholesterol and LDL-cholesterol production, and elevate HDL-cholesterol levels. Table 2 compares the actions of antihypercholesterolemic agents.

Pravastatin and simvastatin are generally well tolerated. They are contraindicated in liver disease or unexplained, persistent elevations in liver-function tests. Liver-function tests should be performed regularly during the first year of therapy, and periodically thereafter.

Uncomplicated myalgia (muscle aching), myopathy (any muscle disease), and/or rhabdomyolysis (necrosis of muscle) are occasionally observed. Unexplained muscle pain, weakness,

**TABLE 2**  
**Comparison of Cholesterol-lowering Drugs**

Drug	LDL	HDL	Triglycerides
Niacin (Nicobid, etc.)	decrease (VLDL)	increase	decrease
Gemfibrozil (Lopid)	decrease (VLDL)	increase	decrease
Lovastatin (Mevacor)	decrease	increase	decrease
Simvastatin (Zocor)	decrease	increase	decrease
Pravastatin (Pravachol)	decrease	increase	decrease
Cholestyramine (Questran)	decrease	none to slight increase	transient increase; return to baseline within 4 weeks
Colestipol (Colestid)	decrease	none to slight increase	transient increase; return to baseline within 4 weeks
Probucol (Lorelco)	decrease	decrease	no effect
Clofibrate (Atromid S)	decrease (VLDL)	no effect	decrease

HDL, high density lipoprotein; LDL, low-density lipoprotein; VLDL, very low density lipoprotein

or tenderness should be reported to the physician.

There are unconfirmed reports of patients receiving both an HMG-CoA reductase inhibitor and gemfibrozil (Lopid) developing myopathy and renal failure. The mechanism for this interaction has not been identified, nor is there a proven cause and effect relationship. Nonetheless, the manufacturers of both drugs state in their package insert that possible benefits of combined therapy do not outweigh the risks, that there is no assurance that periodic monitoring of renal function will prevent the occurrence of severe myopathy/renal damage, and that combined use should be avoided.

There is concern that use of cholestyramine (Questran) and colestipol

(Colestid) may reduce the therapeutic effect of concomitant HMG-CoA reductase inhibitors by binding with them to reduce absorption. Doses of the latter should be given at least one hour before or four hours after bile acid sequestrant resins.

In contrast to lovastatin which should be taken with food to enhance absorption, the newer drugs can be taken without regard to food. Pravastatin and simvastatin are best taken as a single bedtime dose. Timing is important to maximize therapy since the peak time for hepatic cholesterol synthesis is approximately between 2 a.m. and 6 a.m..

Pravachol is supplied as 10 mg and 20 mg tablets. Zocor is available in 5 mg, 10 mg and 20 mg tablets; plans



are underway to market a 40 mg dosage strength.

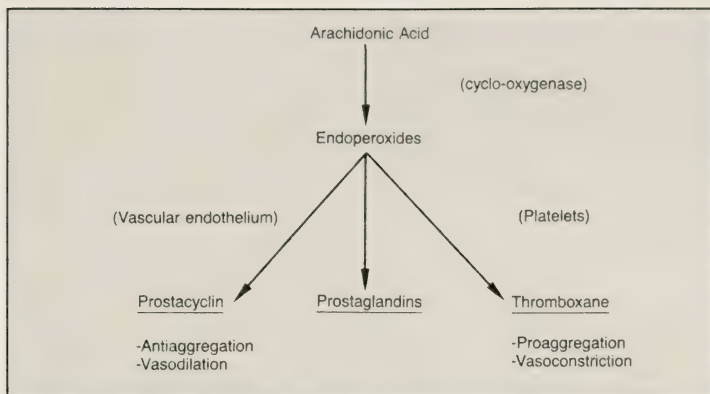
Patient should follow a standard cholesterol-lowering diet for this medication to work properly. In the event that a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The following signs and symptoms should be reported to the physician if they occur: blurred vision, muscle pain, tenderness or weakness, fatigue, fever, stomach pain, headache, nausea or skin rash.

### Antianginals

**Isosorbide mononitrate (ISMO--Wyeth-Ayerst).** Isosorbide mononitrate (hence its trade name ISMO) is the major active metabolite of isosorbide dinitrate. It is indicated for prevention of chronic, stable angina pectoris attacks due to coronary heart disease. It is not approved to abort acute anginal attacks because of its slow (one hour) onset of action. Most of the clinical activity of the dinitrate salt is due to conversion to the active mononitrate metabolite. The claim is made that there is less chance for tolerance to the mononitrate salt, presumably because isosorbide dinitrate induces its own metabolism in some patients.

Tolerance reportedly does not develop as rapidly with the mononitrate salt if the dosing schedule is complied with: twice-daily administration with the first dose in the morning and the second seven hours later. This provides a nitrate-free period toward the end of the day which also reportedly minimizes significant rebound/withdrawal effects. Isosorbide mononitrate is marketed as 20 mg tablets.



### Nonsteroidal Antiinflammatories

The pharmacologic actions of nonsteroidal anti-inflammatory drugs (NSAIDs) are essentially identical when measured objectively. Therapeutic responses are often subjective because there is considerable interpatient variability in response (i.e., extent of symptom control) to each drug. When one looks at the average therapeutic effect of all NSAIDs, a clinically significant difference cannot be determined. However, certain patient populations may experience better results from one particular NSAID than another.

This is partly due to the inability of some patients to tolerate certain NSAIDs, and the highly subjective manner in which therapeutic outcomes are measured for most indications. Sincere there is no instrumentation to accurately measure pain relief or feeling of "well being," the patient's opinion of symptomatic relief is the only measure of effectiveness. When a new NSAID is marketed, it is hoped that it will control symptoms, provide relief in patients who fail to respond to other NSAIDs, or have fewer adverse effects.

When a particular NSAID fails to work or the patient becomes tolerant

to it, it is usually best to try a drug from a different chemical class. The same is true when an NSAID exerts excessive adverse effects or toxicity. Therefore, it is important to learn the chemical classes of these drugs.

**Etodolac (Lodine--Wyeth-Ayerst).** This is the first member of a chemical class called the *pyranocarboxylic acid* group. It is structurally similar to the phenylacetic acid derivatives such as diclofenac (Voltaren), and indoleacetic acid derivatives such as indomethacin (Indocin). Etodolac is approved for treatment of osteoarthritis and as a general analgesic. Rheumatoid arthritis is not an official indication. Etodolac, like other NSAIDs, interferes with the synthesis of prostaglandins associated with inflammation by inhibiting the enzyme cyclooxygenase.

NSAIDs are known to cause GI tract upset, bleeding, and gastric ulcers. Part of this action is due to local irritation on the gastric mucosa. Most NSAIDs not only inhibit formation of the prostaglandins responsible for pain and inflammation, but also prevent synthesis of prostaglandins which are cytoprotective to the gastric mucosa. These prostaglandins dilate blood vessels supplying the gastric mucosa with nutrients. They stimulate maturation of gastric epithelial precursor cells, thus resisting ulceration. They increase bicarbonate production at the surface of gastric cells to reduce pepsin's proteolytic action. And, they enhance secretion

of thick mucus that physically protects gastric epithelial cells from the action of acid and pepsin.

Inhibiting these cytoprotective prostaglandins can lead to gastric ulceration. Etodolac (and nabumetone) are reportedly less inhibitory than other NSAIDs.

An analog of the cytoprotective prostaglandins (i.e., misoprostol/Cytotec) is indicated to prevent NSAID-induced gastric ulceration because it mimics the action of the prostaglandins that NSAIDs inhibit.

Gastric bleeding and other signs of GI tract irritation have been observed in some patients, albeit rarely. Still, etodolac, like all other NSAIDs, must be used with caution in persons with a history of peptic ulcer disease or other serious gastrointestinal pathology.

Etodolac is 99 percent plasma protein bound. It competes with warfarin for its binding sites, thereby elevating the blood level of free warfarin. In studies to assess the importance of this interaction, the

anticoagulant effect of warfarin was not significantly affected. Nonetheless, because of the potential for increased gastrointestinal bleeding, concurrent use with warfarin should be avoided.

Like other NSAIDs, etodolac is contraindicated in persons who are allergic to aspirin. NSAIDs as a group cause fluid retention. They must, therefore, be used cautiously by persons with hypertension or congestive heart failure. The extent of absorption of etodolac is not significantly affected by food, although the time to peak concentration is increased.

Lodine is supplied as 200 and 300 mg capsules. The dose is 200 to 400 mg every 6 to 8 hours for analgesia, and 800 to 1200 mg daily in divided doses for osteoarthritis.

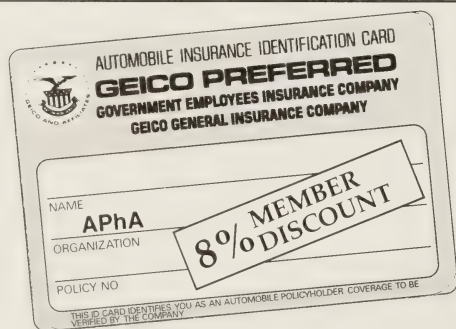
**Nabumetone (Relafen--SmithKline Beecham).** This is the first member of a class of NSAIDs called the *naphthylalkanones*. It is approved for treatment of rheumatoid arthritis and osteoarthritis. Nabumetone is a

potent anti-inflammatory agent with similar action to other NSAIDs, i.e., inhibition of the enzyme cyclooxygenase, leading to decreased prostaglandin synthesis. It also has analgesic properties.

Nabumetone is a weak inhibitor of cyclooxygenase. Its metabolite, 6-methoxy-2-naphthylacetic acid, is a strong inhibitor and responsible for the drug's pharmacologic activity. Nabumetone is activated in the liver, and is therefore referred to as a pro-drug, a concept to be explained shortly.

Taking the drug with food increases its rate of absorption. Excretion is accomplished primarily via the kidney. In the elderly and in patients with severe renal dysfunction, elimination may be delayed with the half-life prolonged and plasma concentrations increased.

Adverse effects are rare and include nausea, upset stomach (dyspepsia), abdominal pain and diarrhea. Photosensitivity reactions, dizziness, edema, headache, tinnitus, nightmares



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and rash have been rarely noted.

The product's manufacturer claims that nabumetone is less likely than other NSAIDs to cause peptic ulceration and serious gastrointestinal bleeding. Since nabumetone is an inactive, nonacidic pro-drug, it should not exert local action on the stomach. Endoscopic evaluation of patients with arthritis has substantiated the claims of reduced GI tract toxicity. Many patients display fewer gastric erosions and ulceration, and less microhemorrhage with nabumetone than with other NSAIDs used in comparative trials. Since gastric effects of NSAIDs are caused by systemic as well as local activity, post-marketing surveillance should clarify the extent of the drug's action on the gastric mucosa.

Relafen is available as 500 mg tablets at the time of writing of this lesson; 750 mg tablets will soon be on the market also. It is administered in total daily doses of 1000 to 2000 mg (given once or twice daily). Since it has a long half-life, its manufacturer recommends two 500 mg tablets, once-daily in the morning, as the initial dosage regimen.

Compliance with antiarthritic therapy is very important. Depending on the type of arthritis being treated, it may take several weeks to months for the patient to feel relief. Once this is achieved, proper blood levels of the drug must be maintained. Patient should be urged to take Lodine and Relafen exactly as directed and not only when pain or swelling occur.

Aspirin may lower blood levels of some NSAIDs. It is recommended that Lodine and Relafen not be taken concurrently with aspirin, except under supervision of a physician. Patients allergic to aspirin or other nonsteroidal agents may also be allergic to Lodine and Relafen.

Both Lodine and Relafen can be taken with or without food. Each dose should be followed with one-half to one full glass of water.

Warning signs of toxicity that should be reported to the physician

include ringing or buzzing in the ears, blurred or changed vision, unusual weight gain or edema in the extremities, skin rash, persistent fever, headache or sore throat, difficult breathing, and black, tarry or bloody stools. Rarely, patients taking NSAIDs experience dizziness, blurred vision or drowsiness. If they do, they should be careful driving or performing hazardous tasks.

If the patient misses a dose, it should be taken as soon as possible. But, if it is almost time for the next dose, the dose should be skipped and the regular dosing schedule resumed. Patients should not take a double dose.

### *Antidepressants*

**Sertraline (Zoloft--Roerig-Pratt).** The precise mechanism of action of this new antidepressant is unknown. Like fluoxetine (Prozac), sertraline is a selective inhibitor of serotonin (5-hydroxytryptamine; 5-HT) re-uptake into CNS nerve endings. This increases the amount of serotonin in the central synaptic spaces.

Determining the exact mechanism of action of psychoactive drugs is not possible since there is no way to quantify depression, anxiety, and other mental disorders. Moreover, the human brain is so complex that it is impossible to simulate mental disorders in animal models.

Likewise, the causes of mental disorders are not understood. A leading theory is that depressed or anxious patients have an imbalance of neurotransmitters within their CNS.

To quickly review, neurotransmitters are chemicals that are released from the terminus of neurons, travel across minute spaces (synapses), and react with chemical configurations (neuroreceptors) on other nerve fibers to elicit a response. This response can be stimulatory or inhibitory, make the person feel better or worse, initiate a motor activity, accomplish a cognitive function, and in

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general, enable the individual to perceive reality from environmental input including vision, hearing, touch or smell.

Numerous neurotransmitters have been identified. Among the most important within the CNS are norepinephrine and serotonin, with dopamine, gamma-aminobutyric acid (GABA), acetylcholine, and histamine also playing a role. This is oversimplified since many other peptides and nonpeptides have been linked to CNS activity. Nonetheless, it provides a foundation for understanding antidepressants and their adverse effects. Oftentimes, it is the adverse effects that determine the antidepressant of choice for a patient. If the patient cannot tolerate them, the chance of complying with the therapeutic regimen is slim.

An in-depth discussion of the biogenic amine theory of mental disorders and the concept of up-regulation and down-regulation of neuroreceptors is beyond the scope of this review. These theories are based on the principle of a "normal" person having his or her own specific balance of neurotransmitters and respective receptor sites.

From time to time, "normal" people become anxious or depressed. However, patients with affective mental disorders cannot return to proper balance. They may remain anxious or worsen to the point of mania, remain depressed so that they are unable to function, shift between mania and depression, or suffer a number of conditions between these extremes.

Until recently, it was believed that antidepressants prevented reuptake of neurotransmitters into neuronal storage sites. The resulting increase in neurotransmitters in the CNS synapses was felt to enhance transmission of nerve impulses, elevate the patient's mood, and overcome depression. There is growing evidence that it is not the true end result of antidepressants. While they do block neurotransmitter reuptake within minutes to hours after administration, it takes several weeks for peak therapeutic

benefits to occur.

A newer theory suggests that antidepressants affect the number and sensitivity of neuroreceptors. It is thought that therapeutic activity results from increasing (up-regulation) or decreasing (down-regulation) these neuroreceptors. The net result is that the abnormal neuroreceptor-neurotransmitter relationship is corrected thereby restoring "balance."

Antidepressants have various specificities in blocking biogenic amine reuptake. For example, tertiary amine antidepressants such as amitriptyline (Elavil, etc.) and imipramine (Tofranil, etc.) have higher activity for serotonin re-uptake but lesser activity for norepinephrine. Secondary amines such as amoxapine (Asendin, etc.) and desipramine (Norpramin, etc.) exert greater blockage of norepinephrine than serotonin. Maprotiline (Ludomil, etc.) is most specific for norepinephrine. Bupropion (Wellbutrin) has little activity on either norepinephrine or serotonin re-uptake. Trazodone (Desyrel, etc.), fluoxetine and sertraline are highly specific blockers of serotonin with little, if any, action on norepinephrine.

There has been a shift in the use of antidepressants in ambulatory patients over the past few years from monoamine oxidase inhibitors and cyclic antidepressants toward the serotonergic agents trazodone and fluoxetine. The same is anticipated for sertraline. A major reason for this is, unlike earlier antidepressants, they do not block acetylcholine, histamine, or dopamine. Therefore, they cause fewer anticholinergic side effects, less sedation, and less orthostatic hypotension and cardiotoxicity. They are better tolerated and safer for depressed patients, some of whom have suicidal tendencies. In clinical trials, common adverse effects reported at greater than 10 percent incidence include headache, tremor, nausea, diarrhea, insomnia, agitation, nervousness, dry mouth and sexual dysfunction in males.

Sertraline has been compared to

tricyclic antidepressants in a number of clinical trials. Study results confirm that the new drug is at least as effective as tricyclics.

Serotonergic drugs are contraindicated for concurrent use with monoamine oxidase inhibitors. The combination can cause a "serotonin syndrome" that includes elevated body temperature, instability, rigidity, confusion, delirium, and coma.

While sertraline absorption is enhanced by taking it with food, its total activity is not significantly affected. Peak plasma concentrations are achieved in five to eight hours after an oral dose. The elimination half-life is 24 hours.

Zoloft tablets are supplied in 50 and 100 mg strengths. The usual dose is 50 mg/day with total daily intake not to exceed 200 mg. The drug can be taken in the morning or evening. If the patient experiences insomnia, the dose should be taken in the morning.

Some patients may experience dizziness, blurred vision or drowsiness. They should be careful driving or performing hazardous tasks until they know how they will react to it. Alcohol may increase this drowsiness.

Patients should be instructed to take Zoloft exactly as directed and not increase or skip doses, or abruptly discontinue therapy without contacting their physician. It may take several weeks before full therapeutic effects are realized and patients taking high doses or on long-term therapy may experience adverse effects if the drug is abruptly discontinued.

Zoloft may cause lightheadedness. The patient should sit or lie down at the first sign, avoid sudden changes in posture, and be careful going up and down stairs. Patients on antidepressants should not take non-prescription cough/cold, hay fever, diet, or sleep-aid products without asking their physician or pharmacist. The tricyclic antidepressants are more likely to cause increased anticholinergic effects

*Continued on page 19....*

## MPhA Continuing Education Quiz

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1. All of the following are ACE inhibitors *except*:
  - a. Altace
  - b. Lotensin
  - c. Accupril
  - d. Plendil
2. Ticlid acts by inhibiting:
  - a. cyclooxygenase
  - b. phosphodiesterase
  - c. platelet adherence
  - d. combination of fibrinogen
3. In addition to their primary action, ACE inhibitors also inhibit production of:
  - a. aldosterone
  - b. cortisol
  - c. insulin
  - d. thyroid hormone
4. Because of the activity referred to in question #3 above, ACE inhibitors can cause:
  - a. hyperthyroidism
  - b. diabetes
  - c. hyperkalemia
  - d. pheochromocytoma
5. Of the following, which is the most important information to convey to patients receiving a prescription for Plendil?
  - a. avoid excessive exposure to sunlight
  - b. do not crush or chew the tablet
  - c. this may discolor the urine and/or feces
  - d. do not take antacids with Plendil
6. Patients receiving a prescription for pravastatin should be advised that the best time to take the dose is:
  - a. at bedtime
  - b. before meals
  - c. on arising
  - d. after meals
7. The enzyme that catalyzes conversion of angiotensinogen to angiotensin I is:
  - a. angiotensin converting enzyme
  - b. angiotensin catalase
  - c. HMG CoA reductase
  - d. renin

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8. Plendil is most closely related chemically and pharmacologically to:
  - a. Calan
  - b. Ioptin
  - c. Cardizem
  - d. Procardia
9. All of the following are true statements about the recently released ACE inhibitors *except*:
  - a. like lisinopril, they can be given on a once-daily dosage
  - b. like captopril, they are controlled-release dosage forms
  - c. like enalapril, they are prodrugs
  - d. like previously marketed ACE inhibitors, they affect bradykinin metabolism
10. Patients receiving which of the following drugs should be advised to have blood tests performed every two weeks for the first three months of therapy:
  - a. Monopril
  - b. Plendil
  - c. Ticlid
  - d. Zocor
11. Zolofit exerts its greatest activity on which of the following neurotransmitters?
  - a. dopamine
  - b. gamma-aminobutyric acid
  - c. norepinephrine
  - d. serotonin
12. The other antidepressants that also acts predominately on the neurotransmitter referred to in question #11 above is:
  - a. Wellbutrin
  - b. Prozac
  - c. Ludiomil
  - d. Asendin
13. NSAIDs reportedly cause gastric ulceration by inhibiting the body's cytoprotective chemicals which are responsible for all of the following *except*:
  - a. decreasing bicarbonate production by gastric cells
  - b. stimulating gastric epithelial precursor cells
  - c. reducing the proteolytic action on pepsin on the gastric cells
  - d. enhancing secretion of the thick mucus that protects gastric epithelial cells
14. Which of the following drugs is best described as a pro-drug?
  - a. Lodine
  - b. Mazicon
  - c. Relafen
  - d. Zolofit
15. The boxed warning in the package insert for Mazicon addresses the potential for its use being associated with increased occurrence of:
  - a. blood disorders
  - b. depression
  - c. seizures
  - d. withdrawal symptoms
16. Lodine and Relafen are similar in that they both inhibit the enzyme:
  - a. beta-lactamase
  - b. cyclooxygenase
  - c. monoamine oxidase
  - d. xanthine reductase
17. Inhibiting the enzyme referred to in question #16 results in decreased production of:
  - a. prostaglandins
  - b. leukotrienes
  - c. histamine
  - d. lymphocytes
18. The two most important neurotransmitters in the CNS that are modified by antidepressants are:
  - a. acetylcholine and histamine
  - b. dopamine and GABA
  - c. endorphins and neurokinins
  - d. norepinephrine and serotonin
19. Mazicon is an antagonist for:
  - a. benzodiazepines
  - b. antidepressants
  - c. barbiturates
  - d. narcotics
20. Compared to previously available NSAIDs, Relafen reportedly causes less of which of the following adverse effects?
  - a. allergic reactions
  - b. esophageal gastroparesis
  - c. peptic ulceration
  - d. Zollinger-Ellison syndrome
21. Which of the following drugs is indicated for treating refractory childhood acute lymphoblastic leukemia?
  - a. Fludara
  - b. Nipent
  - c. Proleukin
  - d. Vumon



22. The labeling of which of the following drugs has a boxed warning about its potential for causing nephrotoxicity?
  - a. Aredia
  - b. Fludara
  - c. Ganite
  - d. Proleukin
23. Which of the following drugs is a product of rDNA technology that was originally named T-cell growth factor?
  - a. Fludara
  - b. Nipent
  - c. Proleukin
  - d. Vumon
24. Which of the following drugs has a boxed warning against its use in combination with fludarabine?
  - a. Aredia
  - b. Ganite
  - c. Nipent
  - d. Proleukin
25. A prescription for teniposide should be filled by dispensing:
  - a. Fludara
  - b. Nipent
  - c. Proleukin
  - d. Vumon
26. Which of the following drugs is indicated for treating B-cell chronic lymphocytic leukemia?
  - a. Fludara
  - b. Nipent
  - c. Proleukin
  - d. Vumon
27. The drug that has a boxed warning about its potential for causing blindness, coma, and death is:
  - a. Aredia
  - b. Fludara
  - c. Nipent
  - d. Proleukin
28. Which of the following drugs is indicated for treating patients refractory to alpha-interferon?
  - a. Fludara
  - b. Nipent
  - c. Proleukin
  - d. Vumon
29. Which of the following drugs has a warning about its association with the capillary leak syndrome?
  - a. Aredia
  - b. Fludara
  - c. Nipent
  - d. Proleukin
30. Pamidronate reportedly inhibits bone resorption by preventing the destructive action of:
  - a. osteoblasts
  - b. osteoclasts
31. Which of the following drugs is a form of the enzyme which is deficient in patients with Gaucher's disease?
  - a. Ceredase
  - b. Proscar
  - c. Chemet
  - d. Supprelin
32. Mivacron and Nuromax are both:
  - a. forms of glucocerebrosidase
  - b. nondepolarizing neuromuscular blockers
  - c. gonadotrophin-releasing factors
  - d. non-barbiturate general anesthetics
33. Which of the following drugs inhibits the enzyme 5-alpha reductase?
  - a. Ceredase
  - b. Proscar
  - c. Chemet
  - d. Supprelin
34. The drug referred to in question #33 above is indicated for treating:
  - a. benign prostatic hyperplasia
  - b. heavy metal poisoning
  - c. malignant pituitary hypoactivity
  - d. premature sexual development
35. The group of drugs that is most likely to be prescribed to alleviate the irritative symptoms of the disease referred to in question #34 above is the:
  - a. alpha-adrenergic agonists
  - b. alpha-adrenergic blockers
  - c. beta-adrenergic agonists
  - d. beta-adrenergic blockers
36. Which of the following drugs form water-soluble chelates with lead?
  - a. Ceredase
  - b. Proscar
  - c. Chemet
  - d. Supprelin

37. Which of the following is a synthetic peptide of the naturally occurring gonadotrophin-releasing hormone?
- Ceredase
  - Proscar
  - Chemet
  - Supprelin
38. The drug referred to in question #37 above is indicated for treating:
- benign prostatic hypertrophy
  - heavy metal poisoning
  - malignant pituitary hypoactivity
  - premature sexual development
39. Which of the following is available in capsules containing beads of medication that can be emptied and taken with soft food by children who cannot swallow the entire capsule?
- Ceredase
  - Proscar
  - Chemet
  - Supprelin
40. Which of the following has the shorter duration of action?
- Mivacron
  - Nuromax

R

## President's Commentary

*Continued from page 4*

eight and one-third percent increase in 1970. The Health Care Finance Administration projects cost increases to slow to seven percent by 1995 and then to six percent by the year 2000.

Pharmacy and drug expenditures are not a *major* factor in the health care cost.

Given that fact, I am concerned that the health care reform proposals developed by our national organizations might just be missing the point. To our elected officials, pharmacy almost an afterthought. Yet, we in pharmacy, somewhat full of our own self-importance, are putting forth two heavily researched tomes to those officials. I worry that pharmacy's message may end up buried amongst all the rhetoric. Our professional education -- thorough research, documentation, covering all the bases -- may actually work against us in conveying pharmacy's views to legislators.

I applaud NARD and APHA for taking a position on national health care reform. Now I call upon them to streamline those positions so that **every** pharmacist in the U.S. can describe pharmacy's health care reform position in just a few sentences. Then it will be up to each of us, and the Association, to take that message over and over to our representatives.

R

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with antihistamines, but caution is also recommended with Zoloft.

There may be a lag time of several weeks from initiation of therapy to full therapeutic response with all antidepressants. This should be communicated to the patient. If the patient does not feel better after three weeks to a month, he or she should be advised to consult their physician.

If the patient misses a dose of Zoloft, they should take it as soon as possible. But if it is almost time for the next dose, they should skip the missed dose and resume the regular dosing schedule. Patients should not take a double dose.

Patients should immediately notify the physician if signs of toxicity occur such as nervousness, confusion, or difficulty getting to sleep. Signs of acute toxicity include agitation, restlessness, or severe drowsiness, troubled breathing, excessive sweating, loss of appetite, hallucinations and/or seizures.

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### ***Benzodiazepine Antagonist***

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**Flumazenil (Mazicon--Roche).** Flumazenil is the first specific antagonist of benzodiazepine receptors within the CNS. The action of benzodiazepines is thought to be due to enhancing transmission of the inhibitory transmitter GABA at its receptor sites. Enhancing its action reduces anxiety.

There are receptor sites in close proximity to the GABA receptors that benzodiazepines bind with to exert their activity. They are so specific that, even though benzodiazepines are not endogenous neurotransmitters, the sites are called *benzodiazepine* receptors. More accurately, they are known as *omega* receptors.

At this time, two omega receptors have been identified. One is associated with sleep, memory, sensory, and motor activity. This explains why

some benzodiazepines are better hypnotics and others better anxiolytics.

Benzodiazepines have a wide margin of safety between effective and toxic doses which explains why they are safer than barbiturate and nonbarbiturate hypnotic/sedatives. Rarely has there been a proven fatality due entirely to benzodiazepine overdose. Most often, the abuse of other drugs or alcohol ingestion is involved.

Nonetheless, there are times when the benzodiazepines do require reversal. Flumazenil has three applications in therapy:

- 1) to reverse benzodiazepine induced general anesthesia; (this result in a shorter recovery period with reduced observation time, and possible diminished morbidity and mortality, possible earlier dismissal from the hospital, and overall decreased costs of medical care.

- 2) to reverse sedation caused by benzodiazepines when used in diagnostic and/or treatment regimens; and,

- 3) to manage benzodiazepine drug overdose by improving the state of consciousness.

Flumazenil binds with benzodiazepine receptor sites in the CNS to displace benzodiazepines, thus terminating their action; it has no agonist activity. It also does not reverse the central actions of other CNS depressants such as alcohol, opioid analgesics, non-benzodiazepine sedatives, or anesthetic drugs.

Adverse effects reported at the 10 percent or greater level include nausea, vomiting, dizziness, and pain at the site of injection. Seizures have been reported in patients receiving flumazenil who have been taking a benzodiazepine for long-term sedation, in patients with tricyclic antidepressant overdose, or persons with both conditions. Flumazenil antagonizes the anticonvulsant effect of benzodiazepines and unmasks the convulsant action of antidepressants. This is considered serious enough for a boxed warning to be required in the

product's labeling.

Additionally, flumazenil should not be given to persons who have received a benzodiazepine for life-threatening conditions such as increased intracranial pressure. It should be used cautiously in patients with a history of long-term benzodiazepine abuse since it may precipitate benzodiazepine withdrawal.

Mazicon injection (0.1 mg/ml) is available in 5 and 10 ml vials, intended to be given by intravenous infusion. The dosage is titrated to individual patient needs.

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### ***Chemotherapeutic Agents***

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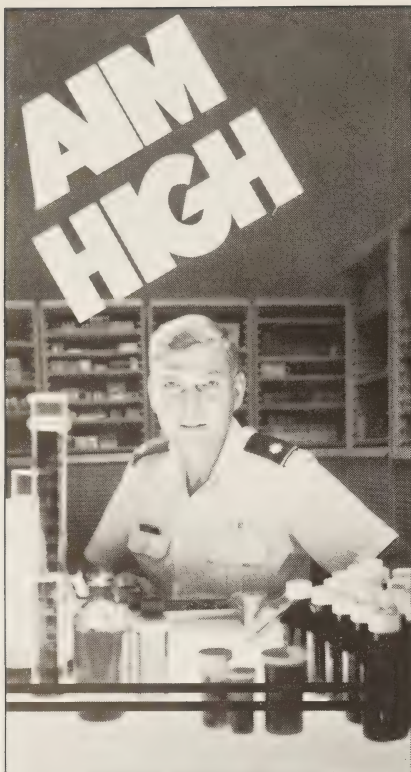
**Fludarabine (Fludara--Berlex).** Fludarabine is an analog of vidarabine (ara-A; Vira-A), and also related to cytarabine (ara-C; Cytosar-U). It is indicated for treatment of B-cell chronic lymphocytic leukemia in patients who have not responded to other treatments, or in those whose disease has progressed during therapy with at least one standard alkylating agent-containing regimen (e.g., Leukeran).

B-cell chronic lymphocytic leukemia is the most common form of leukemia in the Western hemisphere. It occurs mostly in patients over 50, and affects about 50,000 Americans, with another 9,600 new cases diagnosed annually. It progresses slowly, but is invariably lethal.

Standard therapy for B-cell chronic lymphocytic leukemia has included chlorambucil (Leukeran) plus prednisone. With a response rate of 60 to 80 percent, fewer than 10 percent of treated patients experience complete remission. Fludarabine, in combination with prednisone in one study, effected a response rate of 79 percent in previously untreated patients, with a 33 percent complete response.

While its mechanism of action is not completely understood, fludarabine interferes with DNA synthesis.





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Following administration, the drug is rapidly dephosphorylated in the liver. After entering the body's cells, it is re-phosphorylated to its active triphosphate, 2-fluoro-ara-ATP. This is the metabolite that inhibits DNA synthesis.

Adverse effects common with fludarabine include nausea and vomiting, bone marrow depression leading to neutropenia (decreased neutrophils), thrombocytopenia (decreased platelets), and anemia; fever and chills; and increased potential for infection, especially pneumonia. In two clinical trials involving 133 patients, 29 died during the study period. About 50 percent of deaths were due to infection, and 25 percent were from disease progression. A boxed warning appearing in the product labeling includes severe bone marrow depression and severe neurologic effects including blindness, coma, and death. Periodic blood counts should be performed.

Fludara is available as a 50 mg lyophilized powder to be reconstituted with 2 ml of sterile water. This solution is further diluted in 100 to 125 ml of D5W or NSS for intravenous infusion. The infusion should be administered within 8 hours of reconstitution.

Fludara is given in daily doses of 25 mg/M<sup>2</sup> intravenously over 30 minutes for 5 consecutive days, with a 23-day drug-free period between each course of therapy. The total number of cycles of therapy has not been clearly established. After the physician believes that an optimal response has been obtained, three additional cycles should be given before the drug is discontinued. Some patients have received up to 15 cycles of the drug.

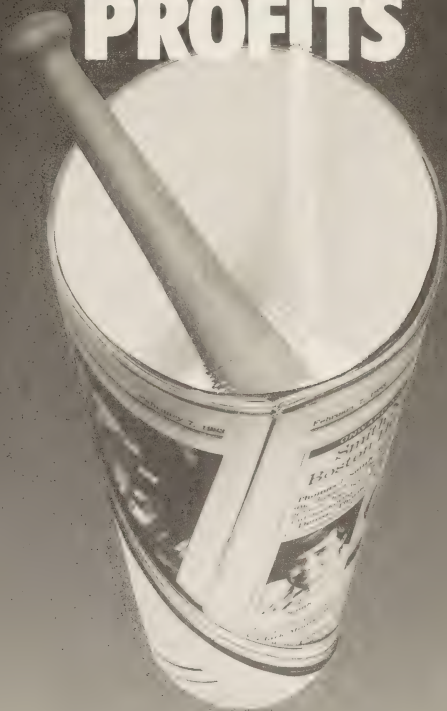
**Pentostatin (Nipent--Parke-Davis).** Approved for treatment of hairy cell leukemia in patients refractory to alpha-interferon (i.e., alfa(alpha)-2a/Roferon-A; alfa(alpha)-2b/Intron A), this new drug, isolated from

cultures of *Streptomyces antibioticus*, blocks DNA synthesis. Inhibition occurs because pentostatin inhibits adenosine deaminase, which leads to increased levels of deoxyadenosine. This, in turn, inhibits ribonucleotide reductase. Since ribonucleotide reductase is required for DNA synthesis, cell reproduction is inhibited.

Hairy cell leukemia annually affects approximately 2,000 patients in the U.S., with 500 to 600 new patients diagnosed each year. In clinical trials, pentostatin produced 58 percent complete response rates in alpha-interferon-refractory hairy cell leukemia patients, and 28 percent partial response rate. In contrast, data for alpha-interferons at the time of clinical trials included 5 to 10 percent complete response with 60 to 70 percent partial response rate.

During clinical trials, there were severe renal, liver, pulmonary and CNS toxicities when pentostatin was used in higher than recommended

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doses. When used in combination with fludarabine, several patients died as a result of pulmonary toxicity. This information is reflected in the box warning in the product labeling.

At the time of writing of this lesson, studies are in progress to evaluate pentostatin in treating other forms of leukemia. It may also have activity in combating organ transplant rejection.

Nipent is marketed in 10 mg vials for intravenous administration. This patient should first be hydrated with 500 to 1000 ml of 5% dextrose in one-half normal saline solution. Commercially available vials should be stored in the refrigerator. Nipent is prepared by dissolving the lyophilized powder in 5 ml of sterile water providing a solution of 2 mg/ml. This should be administered within 8 hours of reconstitution. Doses of 4 mg/M<sup>2</sup> over 20 to 30 minutes every other week are recommended. Each dose should be followed with 500 ml of D5W.

**Teniposide (Vumon--Bristol-Myers Squibb).** Teniposide, obtained from the root of *Podophyllum peltatum*, is a semisynthetic derivative of podophyllotoxin. It is similar to etoposide (VePesid) in mechanism of action, efficacy, and toxicity. Teniposide was approved for treatment of refractory childhood acute lymphoblastic leukemia, in combination with other chemotherapeutic agents. It also has a broad spectrum of antitumor activity against hematologic malignancies and solid tumors, including brain tumors, but is not approved for these indications at this time.

Teniposide is cytotoxic through interaction with DNA. It arrests cell division at the metaphase level. It also impairs mitochondrial electron transport in the respiratory chain.

Bone marrow depression presenting as leukopenia (decreased leukocytes), pancytopenia (deficiency of all blood cells; aplastic anemia), and thrombocytopenia is the dose-limiting factor. Other adverse effects include nausea and vomiting, diarrhea, and phlebitis at the site of injection.

Physicians are warned to be especially aware of the possibility of hypersensitivity reactions which may occur with the first dose, and be life-threatening if not treated properly. Hypersensitivity manifests as chills, fever, tachycardia, bronchospasm, dyspnea, hypo- or hypertension, urticaria, and facial flushing.

Vumon is not marketed at the time of writing this lesson, but the manufacturer has announced that it will be available in 50 mg (5 ml) ampules. Its dosage is highly individualized. Vumon is to be administered over 30 to 60 minutes by intravenous infusion. The patient should be closely monitored during the infusion and at 30-minute intervals afterwards to watch for hypersensitivity reactions.

**Aldesleukin (Proleukin--Chiron-Cetus).** Like the interferons, aldesleukin is a lymphokine. Lymphokines are members of a larger group called the cytokines, and are derived from lymphocytes. The term cytokine denotes the soluble protein molecules released within the immune system to communicate an immune system to communicate an immune or inflammatory response to an antigen. Aldesleukin was originally named T-cell growth of T-lymphocytes. It is also classed pharmacologically as a biologic response modifier; it promotes immune reactions with malignant cells. Aldesleukin is, therefore, not classed as a chemotherapeutic agent in the traditional sense.

Aldesleukin is another product of recombinant DNA (rDNA) technology. It is also the first drug approved for treatment of metastatic renal cell carcinoma in patients who are asymptomatic and ambulatory. This cancer is relatively resistant to current chemotherapy regimens and kills about 10,000 people a year.

In a series of seven clinical trials, aldesleukin reduced tumor size in 15 percent of 255 patients; 4 percent of patients experienced complete reversal of tumors for 23 months. Eleven percent had a substantial reduction in tumor size for nearly 19 months. Response rate ranges from 6 to 20

percent in most studies.

The exact mechanism of action is not known, but aldesleukin stimulates T-cell proliferation and antibody-dependent lymphocyte cytotoxic activity. This results in stimulation of lymphokine activate killer cells as well as natural killer cells. These, in turn, lyse and destroy tumor cells.

The major disadvantage of aldesleukin is its adverse effects which can be life-threatening. In the clinical trials described above, 4 percent of patients died as a result of toxicity to aldesleukin. One life-threatening effect was the capillary-leak syndrome, i.e., the loss the plasma proteins and fluid from the vascular system. Other serious adverse effects include severe nausea and vomiting, angina, hypotension, arrhythmias and myocardial infarction, anemia, respiratory and renal failure, neurologic toxicity, disorientation, and coma. Fever, chills, and malaise often appear within a few hours of administration and can be managed with acetaminophen or a nonsteroidal anti-inflammatory agent. Most adverse effects are reversed within 2 to 3 days of stopping treatment. Continued treatment with aldesleukin does not improve tolerance for adverse effects. Because of its potential for toxicity, aldesleukin is approved for use only in patients with normal cardiovascular and pulmonary functions. There is a strong boxed warning to this effect in the product labeling.

Proleukin will be marketed in single-use vials containing 22 x 10<sup>6</sup> IU aldesleukin to be reconstituted with 1.2 ml of sterile water. This results in a solution containing 18 million units per ml. Its recommended dosage is 600,000 IU/kg diluted in 50 ml D5W to be infused over 15 minutes.

Up to 14 doses may be administered over five days. Following a drug-free interval of nine days, the regimen is repeated. Patient response must be evaluated in four and seven weeks after the course of therapy before retreatment. The extent of antitumor effect and toxic response



are directly dependent upon the amount administered. Some patients respond to additional courses of therapy.

### *Antihypercalcemics*

Two new drugs, gallium nitrate and pamidronate, offer moderate therapeutic advantage over previously available therapy for hypercalcemia associated with malignancy. Hypercalcemia is a potentially life-threatening complication of malignancy, and the most common metabolic complication of cancer. It occurs in 10 to 20 percent of all cancer patients, and in up to 40 percent of women with breast cancer.

Mild or asymptomatic hypercalcemia often responds to intravenous saline hydration with or without diuresis. Urine output of approximately 2 L/day is adequate. When conservative measures fail, more specific antihypercalcemic drugs are used. These include those listed in the table.

**Gallium Nitrate (Ganite--Fujisawa).** This is indicated for the treatment of clearly symptomatic cancer-related hypercalcemia that has not responded to adequate hydration. Gallium nitrate inhibits calcium resorption from bone; its precise mechanism of action is unknown.

In one study, elevated serum calcium was reduced to normal in 75 percent of patients with gallium nitrate, compared to 27 percent response in persons who received calcitonin. Normal levels were maintained for a median duration of 7.5 days with gallium nitrate and one day with calcitonin.

Its package insert contains a boxed warning which cautions that concurrent use of gallium nitrate with other potentially nephrotoxic drugs (e.g., aminoglycosides, amphotericin B) may increase the risk for renal insufficiency in patients with cancer-related hypercalcemia. Gallium nitrate is contraindicated in patients with

severe renal impairment. Hypercalcemia of malignancy is often associated with impaired renal function *per se*. The package insert states that serum creatinine and urine output must be monitored during gallium nitrate therapy. Other precautions include the recommendation for daily serum calcium testing and twice-weekly phosphorus determinations to check for hypocalcemia and hypophosphatemia.

Ganite is available in 25 mg/ml 20 ml vials. The usual dose is 200 mg/M<sup>2</sup> infused intravenously over 24 hours, for five consecutive days. If serum calcium levels fall to within the normal level in less than five days, treatment may be discontinued.

**Pamidronate (Aredia--Ciba-Geigy).** This bisphosphonate is also known as aminohydroxypropylidene diphosphonate (APD), and is related to etidronate disodium (Didronel). Pamidronate is indicated for treatment of moderate to severe hypercalcemia associated with malignancy,

with or without bone metastases. As with other antihypercalcemic drugs, adequate hydration must also be maintained.

Pamidronate's action is to inhibit bone resorption. Although its precise mechanism of action is unknown, it may absorb onto hydroxyapatite crystals (calcium phosphate) in bone, thus preventing the destructive action of osteoclasts. These are the cells that dissolve bone matrix. The number of osteoclasts in bone tissue is reduced after pamidronate therapy.

Action is demonstrable within 24 hours after initiation of therapy, with normocalcemia reported to remain for seven days after administration of a single intravenous infusion. In a comparative study, patients received a single 24-hour intravenous infusion of pamidronate, or a 2-hour infusion of etidronate daily for three hours. Seventy percent of patients receiving pamidronate compared to 41 percent of patients on etidronate were normocalcemic by day seven.

**TABLE 1**  
**Currently Available Drugs with Antihypercalcemic Activity**

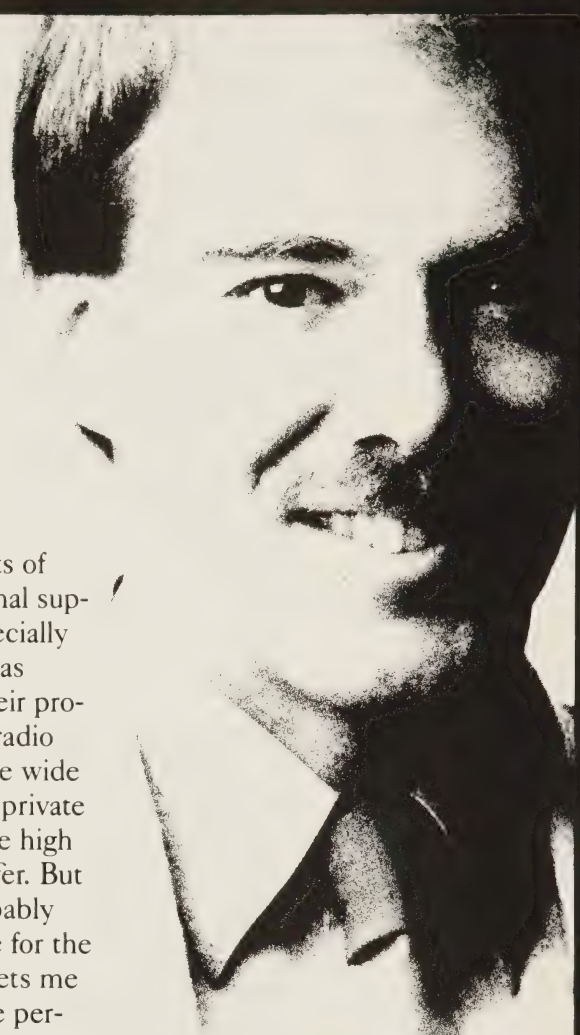
Drug	Strength	Route of Administration	Manufacturer
Calcitonin-Salmon Calcimar	200 IU	subcutaneous	Rhone-Poulenc Rorer
Miacalcin	100 IU & 200 IU	subcutaneous	Sandoz
Calcitonin-Human Cibacalcin	0.5 mg vial	subcutaneous	Ciba-Geigy
Etidronate disodium Didronel Didronel	300 mg/6mL 200 & 400 mg tablets	intravenous oral	MGI Pharma Procter & Gamble
Pamidronate disodium Aredia	30 mg/vial	intravenous	Ciba-Geigy
Gallium nitrate Ganite	25 mg/mL	intravenous	Fujisawa
Plticamycin Mithracin	2500 mcg vial	intravenous	Miles

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Pamidronate differs from etidronate in three important ways. First, most studies confirm that pamidronate is approximately 100 times more potent; thus, lower doses of pamidronate may be effective. Second, unlike etidronate which can inhibit growth of hydroxyapatite crystals and thereby reduce bone formation, pamidronate prevents bone resorption at doses devoid of these other actions. And third, pamidronate has a quicker onset and longer duration of action than etidronate.

Adverse effects reported at the 10 percent or higher level include transient fever, electrolyte disturbance, skin irritation at the site of injection, anorexia, nausea, vomiting, and constipation. Since leukopenia occurred in a few patients, those with pre-existing blood dyscrasias must be monitored carefully for the first two weeks following treatment.

Aredia is available in vials containing 30 mg of lyophilized powder. After reconstitution with sterile water, it is administered in doses of 60 to 90 mg to treat moderate hypercalcemia (serum calcium 12-13.5 mg/dl), and 90 mg to treat severe hypercalcemia (serum calcium >13.5 mg/dl). Injections are given as single-dose intravenous infusions over a 24-hour period.

### Miscellaneous Products

**Finasteride (Proscar--Merck Sharp & Dohme).** Finasteride is the first commercially available 5-alpha reductase inhibitor. It represents a significant advancement in the hormonal regulation of benign prostatic hyperplasia (BPH; hyperplasia = increased number of cells). It is an alternative to surgery and other medical therapies for reduction of gland size in BAH.

BAH is one of the more common health problems of men over 50 years of age. At age 55, about 25 percent of men will notice a decrease in the force of their urinary stream; this increases to about 50 percent by age

75. With nearly 400,000 surgical procedures annually to correct the problem, BAH is the second most prevalent cause of surgery after cataracts.

BAH is a problem because it can partially or completely obstruct the urethra to cause resistance to outflow of urine from the bladder. Symptomatology is complex because severity does not correlate to prostate size. Symptoms are categorized as irritative and obstructive. Irritative symptoms refer to a frequent and urgent need to urinate, and the need to get up often during the night to urinate. Obstructive symptoms include hesitancy, decreased or altered urine stream, and incomplete emptying of the bladder. Most men with BAH experience a combination of symptoms. Complications, while rare, include acute urinary retention, serious urinary tract infections, chronic renal failure, and irreversible impairment of bladder function.

Although transurethral resection of the prostate (TURP) remains the definitive treatment for advanced BAH, patients who have urinary tract symptoms but no strong or immediate indication for surgical intervention

are candidates for finasteride. Medical management of BAH is most successful when symptoms are of relatively recent onset and the size of the prostate has not increased significantly.

By inhibiting the enzyme 5-alpha reductase, testosterone conversion to dihydrotestosterone (DHT) is blocked. DHT is the principal prostatic androgen, and stimulus for cell overgrowth and BAH development. Inhibiting only DHT, and not interfering with testosterone blood levels, minimizes adverse effects associated with generalized androgen blockade. The drug actually results in increased intracellular testosterone concentrations thereby minimizing sexual dysfunction.

Daily dosing with finasteride for six months can reduce serum DHT significantly. By the end of 12 months of therapy, the size of the prostate decreases significantly in some patients. Following discontinuance of the drug, DHT concentrations generally return to normal within 14 days, and prostate size returns to pretreatment size within four months.

In clinical trials to date, adverse effects have been mostly related to sexual activity, including decreased sex drive (libido), decreased volume of ejaculate, and impotence. However, each of these were reported in less than 4 percent of subjects.

Pregnant women should avoid exposure to crushed Proscar tablets because of the potential risk to male fetus from absorbed drug causing abnormalities to their external genitalia. Women of childbearing age should avoid contact with semen of patients taking finasteride.

No significant drug interactions have been identified in clinical trials. However, finasteride is extensively metabolized in the liver, so its potential involvement with the cytochrome P system should at least be considered. Moreover, finasteride is highly bound to plasma protein.

Proscar is available in 5 mg film-coated tablets, and is dosed one tablet daily without regard to meals. While

**Table 1**  
**Important Points About**  
**Finasteride**

- Effectively inhibits 5 alpha-reductase
- Significantly reduces plasma and prostatic DHT (dihydrotestosterone)
- Dose not decrease plasma testosterone
- Does not significantly affect potency or libido
- Shrinks prostate to a size comparable to other forms of androgen blockade
- Increases urine flow and decreases symptoms similar to other forms of androgen blockade
- Produces minimal drug-related adverse effects
- No reported drug interactions

From: McConnell JD: *Urol Clin N America* 1990; 17(3):661.



early symptomatic improvement may be seen, 6 to 12 months of uninterrupted therapy is required to assess potential benefit. Table 1 summarizes important facts about finasteride.

Although not yet approved for this indication, alpha-1 adrenergic blockers (doxazosin/Cardura, prazosin/Minipress, terazosin/Hytrin) may alleviate symptoms of BPH. The smooth muscle in the prostate gland and bladder neck contains large numbers of alpha-1 adrenergic receptors. As stated earlier, the physical size of the enlarged prostate causes obstructive symptoms of BPH. To overcome the poor urine flow, the detrusor muscles of the urinary bladder become more sensitive to alpha-1 adrenergic stimulation and they hypertrophy in order to generate higher voiding pressure. This leads to irritating symptoms (i.e., increased frequency and urgency to urinate).

Studies continue to assess and prove the safety and efficacy of the alpha-1 adrenergic blockers in the treatment of BPH. Meanwhile, it will not be unusual to see these drugs prescribed for concurrent therapy with Proscar.

DHT is a known cancer promotor. There is a degree of "cautious optimism" expressed in the literature that finasteride may be clinically useful for prostate cancer. Studies are reportedly underway to investigate the drug's use for early treatment or prevention of prostate cancer.

Merck has initiated a unique pricing schedule for Proscar that includes the "Patient Support Program for Proscar." This consists of an initial complimentary 30-day supply of drug for new patients placed on Proscar. Six months after being enrolled in the program, patients will be sent a certificate for a complimentary 30-day supply. After that, they will receive a similar certificate every year until at least 1995. The manufacturer will also send these patients a newsletter containing health information.

This medication can be taken with meals or on an empty stomach. It may take six months of treatment or

longer to determine whether the medication is effective. It is important to take the drug at approximately the same time every day.

Proscar has the potential to cause birth defects in male fetuses. Pregnant women or those who can become pregnant should not come in contact with sperm of males taking Proscar and they should not touch ground-up tablets.

Patients should be advised to have their physician enroll them in the manufacturer's Patient Support Program. This will provide them with periodic complimentary medication and a health information newsletter.

**Succimer (Chemet--McNeil Consumer Products Co.)** Also known as 2,3-dimercapto-succinic acid (DMSA), succimer is a heavy metal chelating agent that is indicated for the treatment of lead poisoning in children when blood lead concentrations exceed 45 mcg/dL. Succimer is effective orally. Its activity is based on forming water-soluble complexes (chelates) with lead, which can be readily excreted by the kidney. Succimer has greater specificity in its action than other commercially available chelators. Indicated at present only for chelating with lead, it also has significant affinity for arsenic and mercury.

Lead poisoning is reported to be the most common chronic disease of children under the age of 6 years. Three to four million children in the U.S. are believed to have blood levels high enough to manifest neurological symptoms of lead poisoning. The major sources of exposure include contaminated soil (dust) and lead-based paint.

Adverse effects of succimer include nausea and vomiting, diarrhea, abdominal cramping, and a metallic taste reported in 10 percent of patients. Rash is occasionally reported. Mild increases of serum transaminase have also been noted in about 10 percent of patients. Individuals with a history of hepatic disease should be monitored closely, with serum transaminase levels determined prior to,

and at least weekly throughout therapy. To date, succimer has not caused significant depletion of essential minerals such as calcium, iron and magnesium. This is an advantage over calcium disodium edetate with which can form tight chelates with them thereby reducing their levels.

Chemet is supplied as 100 mg capsules. The drug is administered for a total of 19 days. Initial dosing is calculated at 10 mg/Kg or 350 mg/M<sup>2</sup>, every 8 hours for five days. This is followed by doses at 12-hour intervals for 14 days. Because lead will redistribute from its storage sites (e.g., bone) to the blood following chelation, the blood should be monitored for lead levels at least once weekly until concentrations stabilize. If repeated courses of drug therapy are needed, they may be given with at least a two-week drug-free interval between courses. If the patient cannot swallow the capsules whole, their contents may be sprinkled on soft food, or swallowed from a spoon followed with a flavored beverage.

Succimer is not indicated for prophylaxis. Along with drug therapy for acute lead poisoning, every attempt should be made to identify and remove the source of lead exposure.

Chemet capsules are best taken on an empty stomach with lots of water. However, if the child cannot swallow them whole, they can be opened. The beads can be opened. The beads can be mixed in a small amount of soft food such as applesauce, or swallowed from a spoon followed by a fruit drink. Fluid intake should be maintained with at least 6 to 8 glassfuls of liquid daily.

The problem of poisoning will not be corrected as long as the lead contamination remains in the child's environment. The source of lead exposure should be identified and removed.

**Histrelin (Supprelin--Ortho).** Histrelin joins nafarelin (Synarel), goserelin (Zoladex), gonadorelin (Lutrepulse) and leuprolide (Lupron) as gonadotrophin-releasing factor (GnRF) analogs. This class of drugs

# Ignorance of the Law.....

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has an impressively long list of potential actions

Histrelin is a synthetic peptide of the naturally-occurring gonadotrophin-releasing hormone. Gonadotrophin-releasing hormone (also called luteinizing hormone releasing hormone, LHRH), is an endogenous peptide produced in the hypothalamus. It stimulates the anterior pituitary to release two gonadotrophins, luteinizing hormone (LH) and follicle stimulating hormone (FSH).

Histrelin is indicated for the treatment of precocious puberty (premature sexual development), a condition that affects approximately 6,000 children in the U.S., with 2,000 new diagnoses each year. Children with precocious puberty develop secondary sexual characteristics associated with advanced adolescence. The more serious complications are metabolic. For example, bones do not mature, often resulting in failure of the patient to reach full adult height.

Endogenous GnRH is produced within neurons in the hypothalamus. It passes through the hypophyseal portal vessel system into the anterior pituitary. Here, it binds to receptors to initiate release of gonadotrophins into the systemic circulation. These, then, stimulate gonadal end organ steroid synthesis with increased release of estradiol and progesterone from the ovaries in women, and testosterone from the testes in men.

The mechanism responsible for synthetic (or exogenous) GnRH analog drug action is described as "down regulation" and "desensitization." The synthetic analogs have greater binding affinity for anterior pituitary receptors than the endogenous hormone. Decreases in gonadal steroid production are evident within three months of initiation of therapy, along with slowed skeletal maturation and increased long bone growth allowing patients to reach proper adult height.

Adverse effects reported include skin reactions at the site of injection, muscle cramps, headache, flushing and sweating, indigestion, respiratory

congestion and cough. In approximately 20 percent of female patients, light vaginal bleeding occurred within the first month of therapy.

Supprelin is marketed in three strengths: 120 mcg, 300 mcg, and 600 mcg, each in 0.6 ml. All three strengths are available in 7-day kits. The drug is administered subcutaneously once daily. It is important to change the injection site daily. Therapy can be discontinued when the child reaches puberty.

This medication should be stored in the refrigerator. It should be allowed to warm to room temperature before injection. The dose should be administered at the same time every day. The site of injection should be rotated with each dose.

The vials of this medication are for single use only. Any unused portion should be discarded.

It is not unusual for this medication to cause irritation and swelling at the site of injection. However, if pain is severe or swelling does not subside, the physician should be contacted.

**Doxacurium Chloride (Nuromax--Burroughs Wellcome).** This nondepolarizing neuromuscular blocking agent is an adjunct to general anesthesia for skeletal muscle blockade during surgery. Its mechanism of action is blockade of acetylcholine at the neuromuscular junction.

The most significant adverse effect is extended pharmacologic action beyond the time of surgery. This can result in muscle weakness, and prolonged skeletal muscle paralysis with respiratory depression. This action is more common in geriatric patients.

Long-acting skeletal muscle blockers should not be used in persons with myasthenia gravis; succinylcholine is more appropriate for them. Patients must be carefully monitored if they have been taking other drugs that increase or prolong neuromuscular blockade. These include aminoglycosides, clindamycin and tetracycline, inhalational and local anesthetics, lithium and magnesium salts, and procainamide and quinidine.

The drug is excreted unmetabolized

**Table 2**  
**Potential Therapeutic Applications for GnRH Analogs**

**Male**  
Acne  
Cancer (prostate, testicular)  
Contraception (inhibit spermatogenesis)  
Cryptorchidism  
Hypogonadal (hypopituitary insufficiency)  
Precocious puberty  
Protection from gonadotoxicity of chemotherapy

**Female**  
Acne  
Amenorrhea, primary  
Cancer (ovarian, breast)  
Contraception (inhibit ovulation)  
Dysfunctional uterine bleeding  
Endometriosis  
Fibrocystic breast disease  
Hirsutism  
Polycystic ovarian syndrome  
Premenstrual syndrome  
Precocious puberty  
Uterine leiomyoma

in the urine and bile. Thus, its duration of action may be prolonged in persons with impaired renal or hepatic function.

Nuromax is marketed in 5 ml vials containing 1 mg/ml.

**Mivacurium(Mivacron--Burroughs Wellcome).** This short-acting nondepolarizing neuromuscular blocking agent is an adjunct to general anesthesia to assist in skeletal muscle relaxation during mechanical ventilation or surgery, and to facilitate intubation of the trachea. Mivacurium is the shortest-acting nondepolarizing neuromuscular blocking agent on the market.

Mivacurium is a mild stimulant of histamine release and may cause problems in person with asthma or other conditions aggravated by histamine.

Like succinylcholine, the drug is metabolized by plasma cholinesterase. Its duration of action may be significantly prolonged in persons who have a deficiency of this enzyme, or are taking the drugs listed in the doxacurium monograph.

*Concluded on page 30....*



# No Liability for Addict's Overdose

David B. Brushwood, J.D.



An Iowa woman sued a physician, along with several pharmacists and pharmacies, claiming that these defendants were responsible for the death of her husband. The husband had died of a self-inflicted lethal dose of cocaine. He had been a cocaine addict for several years.

Prior to his death, the husband had worked for physicians as a self-employed computer billing expert. During this period he began to illegally obtain various prescriptions drugs from numerous Iowa pharmacies. He obtained these drugs by either forging physician's signatures or by misrepresenting himself to be a physician over the telephone. However, not of these drugs contained cocaine and none appeared in his body at the time of his death.

The wife claimed that one of the defendant pharmacists, who had discovered that the husband was improperly obtaining prescriptions, failed to alert other pharmacies about the husband's illegal activities. Other pharmacies, the wife claimed, failed to adequately check the husband's requests for prescriptions. As a result, the wife contended that the husband became addicted to prescription drugs and cocaine, and ultimately this addiction led to his death.

The court held that the lawsuit was barred by the public policy of the State of Iowa, which denies relief to those injured in whole or in part because of their own illegal acts.

The general rule is that a person cannot maintain an action if, in order to establish his legal claim, he must rely, in whole or in part, on a claim for damages based on his own wrong or caused by his own neglect, or where he must base his legal action, in whole or in part, on a violation by himself of the criminal or penal laws.

The court ruled that in this case fraudulently obtaining prescriptions from the defendant pharmacies, and using illegal drugs including the self-inflicted overdose of cocaine, constituted an illegal act to which the husband was a party. The lawsuit against the physician, pharmacists and pharmacies was dismissed. **R**

Based on: *Pappas v. Clark*, 1992 Westlaw 383079 (Iowa App. December 29, 1992).

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## New Drugs of 1992

*Concluded from page 28.*

Mivacron is supplied in single-use vials containing 2 mg/ml and a 50 ml premixed infusion with 0.5 mg/ml. It can be given as a bolus or continuous infusion.

**Alglucerase (Ceredase--Genzyme).** Alglucerase is an orphan drug indicated for treatment of symptomatic patients with the non-neurologic form (Type 1) of Gaucher's disease. This is a rare disease affecting less than 10,000 Americans.

Alglucerase is a glycoprotein consisting of 497 amino acids. This is a form of the enzyme glucocerebrosidase. Administering naturally occurring glucocerebrosidase is not effective in treatment of the disease because most of it does not reach the sites of action. The modified enzyme, on the other hand, is stable against premature metabolic destruction so it is readily available for entry into affected cells.

Gaucher's disease is a congenital disorder resulting from a deficiency of glucocerebrosidase. Patients accumulate glucosyl ceramide, one of the normal end-products of lipid metabolism, in lysosomes and reticuloendothelial cells, and especially in macrophages. These macrophages (when filled with lipid they are called Gaucher's cells) gradually displace normal cells in the spleen, liver, and bone marrow. This causes enlarged spleen and liver cells (hepatosplenomegaly) and abnormal function, bone deformity, and blood dyscrasias including leukopenia, thrombocytopenia and anemia.

Ceredase is taken up preferentially by Gaucher's cells in the spleen, liver, and bone marrow where it catalyzes the metabolism of accumulated lipid. It is given intravenously over one to two hours, usually every two weeks, or as needed. Significant improvement is expected within six months of initiating therapy. Treatment must be continued indefinitely.

The therapeutically useful lifespan of alglucerase for treating Gaucher's disease for treating Gaucher's disease may be limited. Bone marrow transplantation offers an alternative therapy, but at higher risk of adverse effects. Moreover, the nucleotide sequence of the gene that codes for the natural enzyme which is deficient in patients with Gaucher's disease is known. Therefore, patients may eventually receive gene-transfer therapy once the procedure is further perfected.

Ceredase is available in 5 ml vials containing 80 International Units per ml for intravenous injection. It should be stored under refrigeration. Solutions should not be shaken prior to use since this will denature the glycoprotein and inactivate it. **R**

## Pharmacists Helping Pharmacists

Experts believe that 10% of Americans suffer from some form of chemical or alcohol problem. The disease of dependence knows no boundaries -- rich or poor, educated or illiterate, black or white are all victims.

Those who suffer from dependency shouldn't be ignored.

If you or some you care about is suffering with an alcohol or drug problem, help is available from friends who care -- the Pharmacists Rehabilitation Committee of Maryland.

For a free, confidential consultation call the Pharmacists Rehabilitation Committee at (410) 727-0746 or 706-7513

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**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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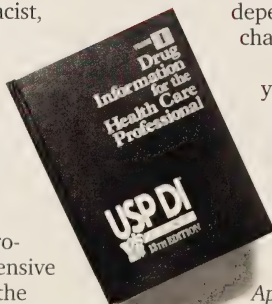


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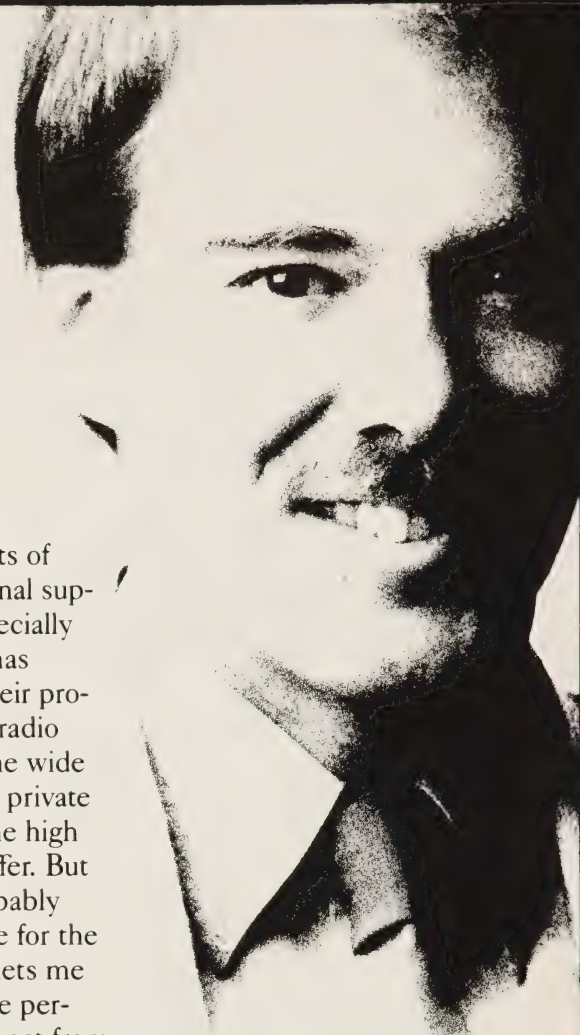
VOL. 69

MARCH, 1993

NO. 3



*The 1993 MPhA  
Third-Party Directory*



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*Scott Rickards*

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# The Maryland Pharmacist

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March 1993

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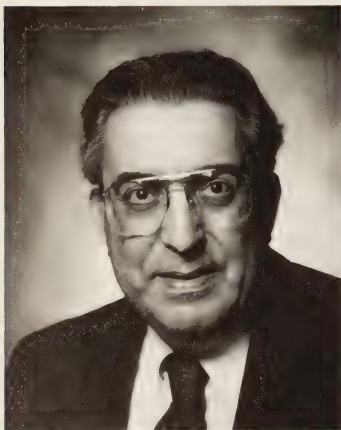
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## President's Commentary

Nicholas C. Lykos, P.D., President



This issue of *The Maryland Pharmacist* is dedicated to the third-party director we have published annually for the past five years.

After it's first publication in the early 1980's, this issue of MPhA's journal quickly became the community pharmacists' "bible." Each year, our directory seems to change dramatically. This year, you won't find Health Care 2000, Iron Workers Local #16, and several other plans; instead, we've added new sections for Express Scripts, DPS, PCS's State Employee Program, and others.

Flipping through this issue is certainly disconcerting. What, when, were and how did this gigantic system of third-party reimbursement develop? Although some insurance companies, including Blue Cross and Blue Shield of Maryland, were experimenting with outpatient prescription insurance in the early 1960's, the real impetus for third-party pharmacy benefits began with the passage of Title XIX -- Medicaid. At about the same time APhA proposed a new system of charging for prescriptions using set dispensing fees. Until then, prescription charges were based upon a percentage add-on to the cost of the drug. The Blues and other prescription program administrators quickly identified the dispensing fee system as an easy-to-follow, and an easy-to-audit, reimbursement mechanism because it was consistent from pharmacy to pharmacy.

It is projected that by year 2000, third-parties will represent 90 to 95 percent of all prescription sales in the United States. This projection will complete the economic transformation of the community pharmacy marketplace that began in the 1960's. For community pharmacy to remain viable, we must all find new ways to interface with third-parties.

What does it take to be a profitable pharmacy in this environment? First, a pharmacy must achieve efficient operating volumes and an efficient prescription volume. If it hasn't or can't achieve those goals, its high operating costs will prevent it from being price competitive in the market. Second, one of the areas that drive expense is personnel salaries, so it must learn to maximize personnel efficiency. Retail pharmacy needs to learn greatly from its colleagues in hospital pharmacies, whom have learned to use supportive technicians effectively. Third, pharmacy must focus on decreasing all other operating expenses. Fourth, pharmacy must learn to control drug product equation costs.

Ultimately, pharmacy must focus on improving patient care and the health status of the patient. It is face-to-face interaction between pharmacists and patients that determine patient satisfaction. Pharmaceuticals are a valuable part of our marketplace but their real value is determined not only by the product but also by how that product is used by our patients.

Ideally, third-parties should channel their patients only to those providers that offer a the highest quality service at the most reasonable price. No longer should the pharmaceutical manufacturers drive the marketplace nor should they drive our reimbursement. Without discriminatory pricing and exclusive pharmacy networks to drive the attention and draw the interest of third-parties, perhaps they will begin to understand the real value of pharmacy -- the pharmaceutical care provided by each pharmacy professional.

R

# Surviving a Third-Party Audit

David G. Miller, P.D., Executive Director



The day can't possibly get any worse. Your partner is leaving tomorrow on a three week vacation. The delivery driver just called to say he had been in an accident. The order from the wholesaler, the one with the vaccines you *promised* to the doctors next door by noon, hasn't arrived and it's already 12:30. Meanwhile, your computer is telling you that Mrs. Allan's prescription is no longer reimbursable even though you filled it for her only two weeks ago.

While juggling the phone with one hand, you open an envelope from Mega-HMO. Finally, you think, here's the check they've been promising for weeks. Think again. It's a letter informing you that Mega-HMO's auditors will be coming to your pharmacy next Wednesday to review your prescription files for compliance with their contract.

In a daze, you pick up on the other phone line. "Hello, this is Carol from BDS Prescription Plan," says a no-nonsense voice. "Representatives from our Review Department will be in your area two weeks from now. They will be arriving at your pharmacy for a complete audit of BDS prescriptions on Monday morning at 9:00 am."

*Sound familiar?*

## First Things First

The first thing to do after receiving notice about a third-party audit is to calm down! Most pharmacists feel a moment of panic whenever an audit is requested. You begin imagining any number of problems... have you forgotten something? what are they looking for? what have I done wrong?

You probably haven't done anything wrong. Just as you are obligated to allow audits of your pharmacy's records by third-parties, those same third-parties may be required by *their* contracts with clients to audit a certain number of pharmacies each year. There may be a number of reasons for why your pharmacy was selected. You may not have had an audit in several years. Your pharmacy may do a high volume of prescriptions with a specific third-party -- especially if you are located near a large employer, a clinic or a medical center. You may have several patients using that third-party who have many expensive prescriptions.

So, what do you do now?

If you are notified by telephone that you are about to be audited, get the name, telephone, and FAX number of the person before proceeding with any more conversation. Inform them that you will need to check your schedule to determine if the time they have selected is appropriate for your pharmacy and that you will contact them shortly to confirm a date and time.

If you are notified in writing, again make sure that you have the name, telephone, and FAX number of the person in charge of coordinating the audit. This usually appears within the notice or on the company's letterhead.

## Read the Contract

Next, get out the most recent copy of your contract with the third-party or insurer. If you don't have one, get one. Call the third-party and ask that a copy be sent to you immediately.



Now would be a good time to check to see that you have copies of **all** your third-party contracts on file in the pharmacy. Pharmacists, unfortunately, tend to be somewhat cavalier about keeping third-party contracts. Remember that they are legal documents to which you have obligated your pharmacy, and possibly yourself, and should be treated the same way you would treat your lease agreement or mortgage papers.

**Read** the contract. All the way through. Does the contract permit audits? They almost always do. Does the contract say anything about what the things auditors will be looking for? Are you completely familiar with the requirements of the contract?

### **Scheduling the Audit**

Most third-party contracts with audit clauses include phrases such as "regular business hours" and "reasonable." This means that while the third-party has a right to audit, you have the right to have the audit conducted in such a manner as to not significantly intrude on your transaction of business. For example, if Monday morning is a hectic time for an audit and Tuesday afternoon is better, you have the right to request that the audit schedule be changed. Also, and this especially applies to small pharmacies, if you will need to schedule additional personnel to be on hand during the audit, you have the right to ask for a schedule change.

When you call the third-party to confirm the audit, make sure you obtain the following information:

- Day and date of the audit.
- Start and end time of the audit.
- The name(s), company if different from the third-party, address, telephone and FAX phone numbers of the auditor(s).
- Written confirmation from the third-party to be sent to your pharmacy via FAX or mail immediately.

### **Asking About Records**

Your next step is to contact the actual auditor(s) if they are different from the person who scheduled the audit. Confirm the date and time of the audit with them, especially if you have changed the originally proposed schedule.

So far so good; but, this next part is more difficult. Ask the auditors to provide you with a list of prescription numbers that they will want to research. Why?

First, though the third-party has the right to review all documentation, including the patient's profile and the original prescriptions for any claim that you submitted to the third-party, they do not have the right to see any prescription or profile information from any other patient. For example, PCS may not review prescription records for Blue Cross patients nor may they review records for cash paying customers.

You, as the pharmacist, have the responsibility of keeping your patient's prescription records confidential. Imagine the ramifications of an auditor flipping through your prescription files and

discovering that their neighbor -- a cash paying customer -- is receiving AZT, thioridazine and diazepam. What might your liability be if that auditor went home and proceeded to tell the neighborhood about your patient?

Second, having the prescription numbers in advance enables you to pull those records to have them available for the auditors when they arrive. It's more efficient and helps save you time and effort in tracking down files and records if this can be done ahead of time.

Be aware, however, that in most cases the auditors will not want to give you the prescription numbers for fear that you could then pull these records and correct errors or improprieties. Blue Cross and Blue Shield of Maryland has a model pharmacy auditing process that provides the pharmacy with the majority of prescription numbers in advance and will also ask for some numbers at the time of the audit. This system speeds up the process for the pharmacist while still satisfying the auditors' concerns about "tampering."

Whether or not you are successful

### ***Audit Checklist***

Do you have access to or know where you can find.....

- ☐ Most recent copy of the third-party/pharmacy contract and any plan data sheets sent to you from the third-party.
- ☐ Third-party signature logs, including logs for delivered prescriptions if you have delivery service
- ☐ Pharmacy licenses and permits
- ☐ Pharmacist licenses
- ☐ Liability insurance policies for both the pharmacy itself and professional liability insurance policies for the pharmacists.
- ☐ Copies of rejected or unpaid claims from the auditing third-party as well as any documentation you may have regarding problems with the third-party's payments, processing system, etc.

in obtaining prescription records in advance, you should insist on receiving that information.

In addition to a list of prescription records, ask what other specific information or data the auditor will require. The checklist on page 6 lists some of the most commonly requested items. Whether or not you are facing an audit, the time spent today in putting copies of these documents into a readily retrievable file folder is a wise investment for tomorrow.

Before you conclude your conversation with the auditor, ask how long they anticipate spending in your pharmacy. As you may wish to have additional staff on hand during the audit, this time frame will give you some idea of scheduling needs.

### The Actual Audit

The big day finally arrives and so do the auditors. Before beginning the audit, ask for identification from the auditor(s) and one of their business cards for your files. Keep these along with your contract and any written communications you have received from the third-party about this or previous audits.

The first rule of conducting an audit -- one that is broken by just about every pharmacist -- is to *never* allow the auditor access to your records without close supervision from pharmacy personnel. Pharmacists have called MPhA after receiving a third-party audit report that requests back-payment for claims. During the course of their audits, the pharmacists allowed the auditors to look at any and all prescriptions. From the data on those prescriptions, the auditors were able to determine that the pharmacy was not giving them the lowest price. Even though it means having additional staff on hand, and possibly tying you up for an entire day, you or another pharmacist should sit down with the auditor, extract the information they request and *only* that information, and personally give it to the auditor. Remember, you have an obligation

to preserve your patients prescription history confidentiality. Likewise, you also have an obligation to protect your business that could be jeopardized by an auditor on a "witch-hunt," willing to use any information in any way to recoup money for their business.

If during the course of the audit you and the auditor discover that a mistake has been made on a prescription or a claim, be sure that you record what the mistake or problem is and what explanation, if any, you give to the auditor. Bear in mind that because most third-party auditors are not familiar with Maryland's pharmacy laws and regulations, they may raise questions about how you record information.

For example, one pharmacist told the MPhA office about an auditor who wanted to deny payments for all refills previously submitted to the third-party because the pharmacist had only recorded them in the computer and not on the back of the actual prescription. The auditor didn't believe that this was a legitimate method for documenting refills until the pharmacist was able to show that the Maryland State Board of Pharmacy considered this system acceptable. Therefore, you, as the pharmacist, should have on-hand during the audit a copy of the most current pharmacy laws and regulations.

Before the audit is concluded, make sure that you show the auditor any rejections or denied claims from the third-party. Also make sure you show the auditor any records of outstanding claims that you have not been paid for. Ask for explanations as to why the claims were rejected, denied, or why you have not received payment. Give copies of these to the auditor and ask that they be made part of his or her final report. Ask also that you receive a **written** copy of the auditor's final report. Ask when you should expect the report and what appeals process is available should it become necessary.

### Audit Rules To Remember

- Never allow the auditor access to records or files that do not pertain to the third-party or its customers.
- Always request identification from the auditor before allowing them access to your records.
- Never volunteer information that the auditor hasn't asked for.
- Always take notes during the audit about problems or questions raised by the auditor and your explanation, if any.
- Never lie or attempt to bluff your way through an audit. If you don't have an answer to the auditor's question, tell him or her when you will have an answer and then follow through.
- Always have a copy of the Maryland pharmacy laws and regulations on hand to reference in case of questions.

### After The Audit

Once the audit is finished, put the copies of your notes plus any material given to you by the auditor with your contract. If you do not receive the written report from the auditor you requested by the time promised, call and ask about the status of your audit. Don't be surprised if you don't hear anything -- that's generally a good sign that means everything was pretty much acceptable.

*Concluded on page 27....*

## Aetna

Aetna Pharmacy Management  
MC17

151 Farmington Avenue

Hartford, Connecticut 06156

(800) 238-6279 *Help Desk, Eligibility verification*

Cost Basis:	Varies by group
Dispensing Fee:	Varies by group
Method of Billing:	On-line
Dependent Age:	19/23
Refills Allowed:	1 year
Generics Required:	Yes, for most groups
Doctor List:	Yes for HMO plans
Pre-Authorization:	For "DAW" prescriptions
Maximum Days/Dosage:	Most plans have a 30 day supply limit. Some plans allow 100 days supply.

Maintenance List:	Some groups, check plan guidelines
-------------------	------------------------------------

Maryland Rx's Only:	Varies by group
Processor:	Aetna

### Special Items

Smoking Cessation:	Varies by group
Rogaine:	No
Retin A:	Pre-authorization required
Cyclosporine:	Varies by group
Retrovir:	Varies by group
Fertility:	Varies by group
Rx Vitamins:	Varies by group
Anorectics:	No
Contraceptives:	Varies by group
Diaphragms/Devices:	No
Insulin:	Yes, up to a 30 day supply
Syringes:	Varies by group
Diabetic Supplies:	Varies by group
Injections:	Varies by group

## Alta Administrators

Alta Administrators

Post Office Box 85132

Richmond, Virginia 23261

(800) 998-5033

Cost Basis:	WAC + 2.6%
Dispensing Fee:	\$5.00
Method of Billing:	On-line
Dependent Age:	Varies by plan
Refills Allowed:	By law
Generics Required:	Yes if available
Doctor List:	No
Pre-Authorization Required:	Varies by plan
Maximum Days/Dosage:	Varies by plan
Maintenance List:	Yes
Maryland Rx's Only:	Varies by plan
Processor:	Alta Administrators

### Special Items

Smoking Cessation:	Varies, some require pre-auth
Rogaine:	Varies, some require pre-auth
Retin A:	Varies, some require pre-auth
Cyclosporine:	Varies, some require pre-auth
Retrovir:	Varies, some require pre-auth
Fertility:	Varies, some require pre-auth
Rx Vitamins:	Varies, some require pre-auth
Anorectics:	No
Contraceptives:	Some plans allow up to 3 packs.
Diaphragms/Devices:	Varies by plan
Insulin :	Yes
Syringes:	No
Diabetic Supplies:	Yes
Injections:	No

*Notes:* No dental prescriptions are covered.



# APS

Associated Prescription Services  
2811 Baltimore Drive  
Baltimore, Maryland 21244  
(410) 944-2700 -- Baltimore  
(410) 621-5150 -- Washington, DC  
(800) 962-3784

Cost Basis:	AWP or AWP-10%
Dispensing Fee:	Varies
Method of Billing:	UCF/tape/electronic
Dependent Age:	Most are 19/23
Refills Allowed:	By law
Generics Required:	See card. If generic, use the Maryland State Formulary.
Doctor List:	No
Pre-Authorization:	If greater than \$300
Days Supply:	See chart below.
Maintenance List:	Yes, see manual
Maryland Rx's Only:	Yes
Processor:	APS

## Special Items

Smoking Cessation:	POS verification
Rogaine:	POS verification
Retin A:	POS verification
Cyclosporine:	POS verification
Retrovir:	POS verification
Fertility:	POS verification
Rx Vitamins:	POS verification
Anorectics:	POS verification
Contraceptives:	Up to 3 packs per prescription
Diaphragms/Devices:	POS verification
Insulin:	Yes
Syringes:	Plan 9, code "S" or "F" only
Diabetic Supplies:	No, unless code "F" on card.
Injections:	Some plans.

*Notes:* \$1.25 compound fee. APS point-of-sale (POS) verification system ascertains whether the patient has coverage for special prescription items. A manual sent to pharmacies by APS lists groups which include or exclude these items but is not as up-to-date as the POS.

All plans cover legend drugs unless specifically excluded by the plan. All plans exclude immunological agents and appliances unless otherwise excluded. All plans include compounded prescriptions if at least one ingredient is a federal Legend Drug in a therapeutic amount. Any drug

or prescription prescribed for other than the Federally approved usage will not be paid for unless authorized by the Fund. Some plans allow "DAW-1" overrides.

## Plan Code Limitations and Exceptions

<b>A</b>	Up to a 100 day supply.
<b>B</b>	Up to a 34 day supply or 100 doses, whichever is greater.
<b>C</b>	Up to a 34 day supply only.
<b>D</b>	Up to a 34 day supply or 100 day supply for Approved Maintenance Drugs
<b>E</b>	Up to a 34 day supply or 100 doses whichever is greater.
<b>F</b>	Insulin syringes and needles, and testing products that are used to detect or monitor diabetes (Clinistix, Chemstrip, etc.) on prescription only.
<b>G</b>	Generic plan (See #9 in policies and procedures)
<b>K</b>	Diaphragms covered for member or spouse only.
<b>N</b>	No vitamins, whether legend or not.
<b>P</b>	No fertility drugs
<b>S</b>	Insulin syringes and needles covered on prescription only.
<b>W</b>	No diet pills.
<b>Z</b>	No smoking deterrents ( <i>ie</i> : Nicorette, Nicoderm).

A chart providing additional information on the various APS plans appears on page 10.

Plan Number	Oral Contraceptives	OTC Products	Injectables	Insulin	Miscellaneous
1	Yes	Yes	Yes	Yes	
2	No	No	No	Yes	
3	Yes	Yes	No	Yes	
4	No	Yes	No	Yes	10% copay, 5% copay at network pharmacies
5	Yes	No	No	Yes	
6	No	No	Yes	Yes	
7	Yes	No	Yes	Yes	
8	No	Yes	Yes	Yes	
9	No	No	No	Yes	No Vitamins

*APS Plan Chart*



## Fill This Script And Watch Your Condition Improve

**Pharmacy Name** \_\_\_\_\_

**Contact Name** \_\_\_\_\_

**Address** \_\_\_\_\_

**City, State, Zip** \_\_\_\_\_

**Phone Number** \_\_\_\_\_

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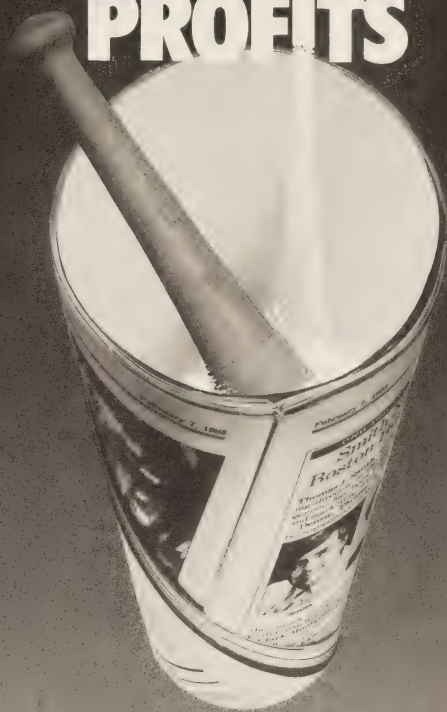


Alco Health Services Corporation



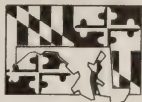
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# Blue Cross of Maryland

Blue Cross of Maryland  
10455 Mill Run Circle  
Owings Mills, Maryland 21117  
(410) 581-3000 *General Information*  
(410) 581-3535 or (800) 248-3410 *Blue Line*  
(410) 581-3542 or (800) 782-9986 *Pharmacy Claims*  
(800) 421-2342 *Provider Relations*  
(800) 421-2342 *BC/BS Eligibility*  
(410) 998-5480 *Fraud and Abuse*  
(410) 560-3790 *Pharmacy Relations/Paradigm*  
(800) 492-4209 *GM Plan Information*

PHS/Caremark  
Post Office Box 80716  
Los Angeles, California 90080  
(800) 421-2342 *Help Desk*  
(800) 835-3330 *Eligibility Verification*  
(800) 421-2343 *PHS Information, Extension 3*

Cost Basis:	Acquisition
Dispensing Fee:	\$ 3.30
Method of Billing:	UCF/tape/on-line
Dependent Age:	19/23
Refills Allowed:	1 year
Generics Required:	Yes, *PPD with a few exceptions
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Lesser of 34 days supply or 100 doses
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PHS for Blue Cross
Mnemonic:	BCBSM

## Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	If "PCD" on card, 3 months
Diaphragms/Devices:	No
Insulin:	Yes, up to 4 vials/copay
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

*Notes:* General Motors employees have a \$5.00 copay *except* if they are members of a PPO and then the copay is \$3.00. All claims should reflect a complete and correct birthdate for the patient. All Blue Cross programs require 1 copay for 34 days supply for items not on maintenance lists. If on maintenance lists, 1 copay per maximum day supply is allowed. **Claims for General Motors, K-Mart, UAW cannot be submitted to PHS.** Send UCF claims to: BCBS of MD, PO Box 1694, Cumberland, MD 21501-1694. Other national accounts go to PHS as above. Worcester County employees still go through PCS. BCBS IMD Program has a \$50 annual deductible and a \$750 quarterly maximum benefit. Copays are 20% of ingredient costs for generics and 30% of cost for brands.

## On the Corner Frank McGinity, P.D.

According to Maryland law, prescribers must write prescriptions legibly *and* must have an identifiable signature. I thought you'd enjoy deciphering this prescription I recently received. The answer to this month's prescription will appear in the April 1993 issue of *The Maryland Pharmacist*.

In the meantime, while you're figuring this one out, send or FAX your unusual prescriptions to "On the Corner," MPhA, 650 West Lombard Street, Baltimore, MD 21201, FAX (410) 727-2253.

*Ventilen 480*  
*2.5 mg 38 tabs*

### Last Issue's Answer

Coumadin 12.5mg, #30, 1/2 tab every morning  
The physician actually wanted 2.5mg

## CareFirst

PHS  
PO Box 80716  
Los Angeles, California 90080  
(310) 391-1133  
(800) 421-2342  
(410) 528-7103 *Local*  
(800) 228-8161 *Local toll-free*  
(410) 560-3790 *Paradigm Management*

Cost Basis:	AWP-10%
Dispensing Fee:	\$3.00
Method of Billing:	UCF/tape/On-line
Dependent Age:	By card
Refills Allowed:	By Law
Generics Required:	CFS Formulary, *PPD
Doctor List:	Yes
Pre-Authorization:	Some drugs, see formulary
Days Supply:	34 days supply
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	PHS for CareFirst Managed by Paradigm.
Mnemonic(s):	HCCMA for CareFirst HCCP for Potomac Health HCCL for Liberty CareFirst

### Special Items

Smoking Cessation:	Yes, with pre-auth
Rogaine:	No
Retin A:	Yes, pre-auth if over age 35
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, if RX/C on card
Diaphragms/Devices:	Yes, if RX/C on card
Insulin:	Yes
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. No anabolic hormones are covered. Some brands are not reimburseable (e.g., Triphasil, Norinyl, Ortho-Novum, insulins). See formulary for alternatives.

## Carpenters Fund

432 Eastern Boulevard  
Baltimore, Maryland 21221  
(410) 686-2700  
(800) 899-4464

Cost Basis:	AWP
Dispensing Fee:	\$2.60
Method of Billing:	UCF/tape
Dependent Age:	19/23
Refills Allowed:	By Law
Generics Required:	Yes, *PPD
Doctor List:	No
Pre-Authorization:	If Rx costs more than \$200
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	90 days supply
Maryland Rx's Only:	Yes
Processor:	Carpenters Benefit Fund

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Pre-authorization only
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	No
Injections:	No

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available.

# Chesapeake Health

PHS/Caremark  
PO Box 80716  
Los Angeles, California 90080  
(310) 391-1133 *PHS*  
(800) 421-2342 *PHS*  
(410) 560-3787 *Paradigm Administration*  
(410) 539-8622 *Local Pre-authorization*

Cost Basis:	AWP-10%
Dispensing Fee:	\$3.00
Method of Billing:	Tape/On-line
Dependent Age:	By card
Refills Allowed:	2
Generics Required:	PHS Formulary, *PPD
Doctor List:	No
Pre-Authorization:	For prescriptions costing more than \$100 except for chronic drugs.
Days Supply:	Greater of 34 days supply or 100 doses. Pre-authorization is required for greater than this except for chronic drugs.
Maintenance List:	Yes
Maryland Rx's Only:	No
Processor:	PHS for Chesapeake Health Plan
Mnemonic:	CHES

## Special Items

Smoking Cessation:	Yes for groups 5500/5078 only
Rogaine:	No
Retin A:	Yes, up to age 25
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes, if "BC" on card.
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, if "BC" on card, 3 packs
Diaphragms/Devices:	Yes, if "R-BC" on card
Insulin:	Yes, up to 4 vials
Syringes:	Yes, 100 maximum per prescription
Diabetic Supplies:	Group 5500 only: test strips, sticks, devices, lancets Group 5078 only: test strips, sticks, tablets
Injections:	No

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Group 5500 series plans cover same items as Medicaid. Chesapeake Health Plan excludes some name brands in favor of identical brands (eg. Calan SR instead of Isoptin SR). Refer to list provided by the program or the on-line information. The Chesapeake Formulary may differ from the standard Columbia/Freestate Formulary. Chesapeake Health Plan covers some medical supplies, no progesterone suppositories. Cards marked "BC" cover birth control pills only. Cards marked "R-BC" cover birth control pills and prescriptions. There are no copayments for nursing home patients. Temporary cards cover oral contraceptives, diaphragms, fertility products, and diabetic tests. Some plans have a \$1,000 annual maximum. Chesapeake requires generic alternatives for certain birth control cycles.

Pre-authorized medical supplies must be billed directly to the appropriate Chesapeake site.

## Switch Agent Directory

NDC ..... (800) 388-2316  
*National Data Corporation*

Envoy ..... (800) 333-6869

GCC ..... (800) 433-4893  
*General Computer Company*

NABANCO ..... (800) 884-8222



## CIGNA Mid-Atlantic

Argus Health Systems  
1055 Broadway  
Kansas City, Missouri 64105  
(800) 522-7487

Cost Basis:	AWP or contracted amount
Dispensing Fee:	Varies
Method of Billing:	UCF/on-line
Dependent Age:	By card
Refills Allowed:	1 year
Generics Required:	Yes
Doctor List:	No, DEA number required
Pre-Authorization:	No
Days Supply:	30 days supply for most plans
Maintenance List:	For some plans
Maryland Rx's Only:	Yes
Processor:	Argus for CIGNA Mid-Atlantic

### Special Items

Smoking Cessation:	Yes, limited plans only
Rogaine:	No
Retin A:	Most, up to age 25 or preautho
Cyclosporine:	No
Retrovir:	Preauthorization required
Fertility:	Yes, for most plans
Rx Vitamins:	Only for some plans
Anorectics:	No, for most plans
Contraceptives:	Yes, but for only a few plans
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	No, for most plans
Diabetic Supplies:	No, for most plans
Injections:	No

Notes: Compound NDC for CIGNA Mid-Atlantic 99999-9999-99.

## DPS

Diversified Pharmaceutical Services  
PO Box 1459, Route 9720  
Minneapolis, Minnesota 55440-1459  
(612) 830-3166  
(800) 233-8065  
(800) 824-0898

Cost Basis:	AWP-10%
Dispensing Fee:	\$2.00
Method of Billing:	On-line
Dependent Age:	By card
Refills Allowed:	1 year
Generics Required:	Yes, *PPD
Doctor List:	No
Pre-Authorization:	Some plans require
Days Supply:	Most plans have a maximum 34 days supply limit. Some plans allow 34 days or 100 doses.
Maintenance List:	100 doses allowed for some plans
Maryland Rx's Only:	Yes
Processor:	DPS
Mnemonic:	Varies with plan. Also has suffix code.

### Special Items

Smoking Cessation:	Some plans
Rogaine:	Most plans, no
Retin A:	Some plans
Cyclosporine:	Yes
Retrovir:	Some plans
Fertility:	Some plans
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Some plans
Diaphragms/Devices:	Some plans
Insulin:	Yes, 34 day supply
Syringes:	Some plans, for insulin only
Diabetic Supplies:	Yes, for most plans
Injections:	Yes

Notes: \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Yocon and growth hormones are not covered. Manual claims should be sent to DPS, Route 4880, PO Box 59005, Minneapolis, MN 55440-0005.

## Express Scripts (PERx)

### Baltimore City Employees

Express Scripts  
2369 Schuetz Road  
St. Louis, Missouri 63146  
(800) 553-3750

Cost Basis:	Acquisition
Dispensing Fee:	\$ 3.00
Method of Billing:	On-line
Dependent Age:	19
Refills Allowed:	1 year
Generics Required:	Yes, *PPD with a few exceptions
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Lesser of 34 days supply or 100 doses
Maintenance List:	Yes, up to 100 consecutive days supply
Maryland Rx's Only:	Yes
Processor:	PERx, a.k.a. Express Scripts

#### Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	No
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	If "PCD" on card, 3 months
Diaphragms/Devices:	No
Insulin:	Yes, up to 4 vials/copay
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

Notes: \*PPD - patient pays difference when a brand name product is available or required.

## Express Scripts (PERx)

### General Information

Express Scripts  
2369 Schuetz Road  
St. Louis, Missouri 63146  
(800) 553-3750

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	On-line
Dependent Age:	Varies
Refills Allowed:	By law.
Generics Required:	Recommended
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	Varies by plan
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PERx, a.k.a. Express Scripts

#### Special Items

Smoking Cessation:	Varies by plan
Rogaine:	Varies by plan
Retin A:	Varies by plan
Cyclosporine:	Varies by plan
Retrovir:	Varies by plan
Fertility:	Varies by plan
Rx Vitamins:	Varies by plan
Anorectics:	Varies by plan
Contraceptives:	Varies by plan
Diaphragms/Devices:	Varies by plan
Insulin:	Yes, up to 3 vials
Syringes:	Varies by plan
Diabetic Supplies:	Varies by plan
Injections:	Varies by plan

Notes: \*PPD - patient pays difference for branded prescriptions when generic is available.



## Because One Size Doesn't Fit All...

New Humulin 50/50 is the tailor-made answer to individual patient needs. A unique combination of equal amounts of Regular human insulin and NPH human insulin, it will be useful in situations in which a greater initial insulin response is desirable for greater glycemic control.

Like Humulin 70/30\*, new Humulin 50/50 offers the convenience and accuracy of a premix. And it can be used in conjunction with an existing 70/30 regimen.



### New **Humulin** <sup>50</sup>/<sub>50</sub>

50% human insulin  
isophane suspension  
50% human insulin injection  
(recombinant DNA origin)

#### *The Newest Option in Insulin Therapy*

**WARNING:** Any change of insulin should be made cautiously and only under medical supervision.

\* Humulin® 70/30 (70% human insulin isophane suspension, 30% human insulin injection [recombinant DNA origin]).



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**Eli Lilly and Company**  
Indianapolis, Indiana  
46285



## Free State HMO

PHS/Caremark  
 PO Box 80716  
 Los Angeles, California 90080  
 (310) 391-1133  
 (800) 421-2342  
 (410) 528-7103 *Local General*  
 (800) 228-8161 *Local General*  
 (410) 560-3792 *Local Pre-authorization (Paradigm)*

Cost Basis:	AWP-10%
Dispensing Fee:	\$ 3.00
Method of Billing:	UCF/tape/on-line
Dependent Age:	By card.
Refills Allowed:	By law.
Generics Required:	CFS Formulary, *PPD
Doctor List:	Yes
Pre-Authorization:	Some drugs, see Formulary.
Days Supply:	34 days
Maintenance List:	See Formulary, allows greater of 100 doses or 34 days supply
Maryland Rx's Only:	Yes
Processor:	PHS for Free State HMO
Mnemonic:	Free

### Special Items

Smoking Cessation:	Pre-authorization required
Rogaine:	No
Retin A:	Yes, pre-auth if over age 35
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Some groups
Rx Vitamins:	Some groups
Anorectics:	Some with pre-authorization
Contraceptives:	Most plans cover, 3 packs for 1 copay
Diaphragms/Devices:	Yes, some plans only
Insulin:	Yes, Novo Nordisk brand only
Syringes:	Yes
Diabetic Supplies:	No, unless on card
Injections:	No

*Notes:* Free State requires generics on all prescriptions except anepleptics and some cardiovasculars. Refer to the Free State Formulary covered drugs and generic policies. Certain brand name drugs require alternates (some oral contraceptives, insulins, etc.). For a vacation supply, use a UCF and mark it "VACATION."

## Kaiser Permanente

Kaiser Permanente Drug/Optical Benefits  
 Post Office Box 9800  
 Washington, DC 20016  
 (800) 368-5787 *Pre-authorization, membership*  
 (202) 364-3485 or 364-4868 *Billing*  
 (202) 364-4865 *NABP Registration*  
 (800) 388-2316 *Line Problems*  
 (410) 281-6116 *Woodlawn Pharmacy*  
 (202) 364-6733 *Override Authorization*

Cost Basis:	AWP
Dispensing Fee:	\$3.00
Method of Billing:	UCF/On-line
Dependent Age:	By card
Refills Allowed:	By law
Generics Required:	Medicaid List, *PPD
Doctor List:	Yes
Pre-Authorization:	Yes, for a few drugs
Days Supply:	60 days supply
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	Kaiser Permanente

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Pre-authorization
Retrovir:	Pre-authorization
Fertility:	Pre-authorization
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes, 2 packs per prescription
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	Yes, except lancets
Injections:	Yes, if self-administered

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Kaiser no longer has reduced copays for Baltimore sites. Some have 50% copays and some have \$50 deductibles. No emergency room prescriptions are permitted. Patient must pay and seek reimbursement from Kaiser directly. \$7.00 higher patient copay in most plans for not using Kaiser in-house pharmacies.

## MD-IPA

### MD-IPA

4 Taft Court  
Rockville, Maryland 20850  
(800) 638-8898  
(301) 294-5029 -- Enrollment

Cost Basis:	AWP less contracted %
Dispensing Fee:	Varies
Method of Billing:	UCF/tape/on-line
Dependent Age:	By card
Refills Allowed:	By law
Generics Required:	Strongly advised
Doctor List:	Yes
Pre-Authorization:	No
Days Supply:	34 days supply or 100 doses
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	MD-IPA

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	No
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes, Clomid only
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes, 3 months/copay
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes, for insulin only
Diabetic Supplies:	No
Injections:	Pre-authorization

*Notes:* Some plans have \$50 deductibles. Cards for plans called "Optimum Choice," "Alliance," or "MAPSI" are all MD-IPA plans. "MR" (MAMSIR) is a branch which services outside groups. The rules are the same as above. MR, OCI and MD-IPA all require different neumonics.

## Maryland Medical Assistance

Maryland Medicaid Administration  
Department of Health and Mental Hygiene  
201 West Preston Street  
Baltimore, Maryland 21201

Abuse	(410) 225-1678 or (410) 333-3020
Eligibility Verification	.. (800) 492-2134 <i>Maryland only</i>
Eligibility Verification	(410) 333-3020 <i>Metro Baltimore</i>
Eligibility Verification	(800) 683-5775 <i>Outside Maryland</i>
Fraud	(410) 225-1686
HMO Operations	(410) 225-1590
Invoice Processing (Operations)	(410) 225-5701
Nutritional Formulations	(410) 225-1743
Operations Division	(410) 225-5701 or (410) 225-5795
Pharmacy Assistance Program	(410) 225-5392
Pharmacy Policy Staff Specialist	(410) 225-1459
Policy Division	(410) 225-1455
Preauthorization	.. (410) 225-1755 or (800) 492-6008
Provider Enrollment	(410) 225-5340
Provider Relations	.. (410) 333-5303 or (800) 445-1159
Refill Invoices	..... contact local health department
Kidney Disease Program	(410) 225-5000
Diabetes Program	(410) 225-5150
Recipient Fraud	(410) 225-1686
Drug Coverage/Pre-authorization	..... (410) 225-1755
First Health Technical Help Desk	.... (800) 884-3238
First Health DUR Help Desk	..... (800) 884-7300

Effective January 2, 1993, Maryland Medical Assistance Program initiated an on-line system for point-of-sale claims submission, prospective drug utilization review, verification of recipient eligibility and product coverage. First Health Services Corporation is the administrator of this Program which will process all Medical Assistance and Pharmacy Assistance claims.

Information supplied by the prospective DUR is to be used to assist the pharmacist in dispensing and to aid in mandatory Medicaid patient counseling.

## General Notes

*Amphetamines:* Prescriptions for central nervous system stimulants and anorectic agents used for weight control are not covered by Medical Assistance. The use to treat narcolepsy or hypokinesia must be indicated on prescriptions for amphetamines by the physicians in *their own handwriting*. Methylphenidate (Ritalin) prescriptions used for the treatment of ADD in children do not need the diagnosis.

*General Notes:* Generic substitution requirements may be overridden by a prescriber if he/she specifies "brand medically necessary" or "brand necessary" and a diagnosis or explanation in his/her own handwriting on each prescription. Analeptics marked "BMN" do not have to have a diagnosis noted by the prescriber. The pharmacist must place an "X" in the block in the lower left corner of the claim.

All "brand medically necessary" prescriptions must be submitted on hard-copy. No on-line or tape billing is allowed!

must bill the State the same price you charge a cash customer before any special discounts. You will be paid the lesser of that amount or the cost as defined by the State plus a professional fee.

*Pre-authorization:* If the usual and customary charge for a prescription is more than \$100 and is written for a 34 or more days supply or the cost is greater than \$400, regardless of the days supply, preauthorization should be obtained by calling (410) 225-1755 or (800) 492-6008 beyond the local calling area.

*New Born Policy:* For newborns, use the mother's recipient number and verify the mother's eligibility through EVS before service. Hold the claim for submission until the newborn is entered into the EVS system (about four weeks).

*H<sub>2</sub> Blockers Policy:* First prescriptions must be marked in prescriber's handwriting "initial therapy." Up to a 34 day supply and one refill is allowed.

After that period, prescriptions must be less than the dosage cited below unless the prescriber writes in his or her own handwriting the specific approved medical conditions. Prescriptions for doses equal to or exceeding the following listings are limited to a less than 34 days supply and one refill.

Zantac (300mg/day)	Tagamet (800mg/day)
Pepcid (40mg/day)	Axid (300mg/day)

*Reimbursable OTC Products:* The following over-the-counter products are covered by Maryland Medical Assistance: insulin, hypodermic needles and syringes, enteric coated aspirin, sole ingredient oral ferrous sulfate products, chewable iron and vitamin tablets for children, family planning drugs and devices.

*Rules for Condoms:* Condoms may be dispensed to Medicaid recipients directly by the pharmacist. Either male or female recipients must personally present an eligible card. Twelve condoms are permitted per prescription. Only lubricated or non-lubricated latex condoms are covered -- no lambskin condoms are permitted.

The pharmacist should use a refill form (DHMH 236) to write up the condom package as a prescription and the patient should sign the form where a prescriber's signature would normally go. Write the word "original" immediately below the refill block on the form. Treat each invoice as a new prescription. The patient is not required to pay any copay.

## Specially Assigned NDC Numbers

Use the following Medical Assistance Assigned Medicaid numbers when submitting claims:

### Prescription Items

Compounds	00998-0000-00
Disposable U-100 1ml syringes	00996-2222-00
Disposable U-100 0.5ml syringes	00996-3333-00
All other hypodermics/syringes	Use NDC or
	if not available, 00996-1111-00
Legend drugs without NDC codes	00999-0000-00
Enteral nutrition products	Use NDC or
	if not available, 00999-1111-00
Non-lubricated condoms	00997-1111-00
Lubricated condoms	00997-2222-00

If more than one order is dispensed at one time (eg. two compounded prescriptions, use the 00 for the final digits of the code for the first prescription, 01 for the second, etc. This will prevent rejections as duplicate invoices.



#### *Home IV Therapies*

Total parenteral nutrition .....	00998-1111-00
Antibiotic therapy .....	00998-2222-00
Chemotherapy .....	00998-3333-00
Pain management therapy .....	00998-4444-00
Fluid replacement therapy .....	00998-5555-00
Hemophilia therapy .....	00998-6666-00
Miscellaneous parenteral therapy .....	00998-7777-00

When dispensing prescriptions for chewable iron with multivitamin tablets and ferrous sulfate prescriptions, use the following NDC codes if the product does not have its own NDC code.

#### *Ferrous Sulfate Products*

Chewable iron with vitamin tablets ....	00997-4001-00
Ferrous sulfate drops .....	00997-4002-00
Ferrous sulfate elixir .....	00997-4003-00
Ferrous sulfate syrup .....	00997-4004-00
Ferrous sulfate tablets .....	00997-4005-00
Ferrous sulfate unit dose tablets ....	00997-4006-00

*Notes:* No DESI drug products are covered. Products from manufacturers who have not signed rebate agreements are not covered. A copayment of \$1.00 is required for each prescription or refill from recipients in federal categories except for prescriptions for: individuals under 21 years old, pregnant women, institutionalized individuals, HMO enrollees, family planning drugs and devices. Services to recipients in federal categories cannot be denied because of inability to pay the copayment. Individuals who can afford the copayment are not exempted from paying the copay.

Pharmacy Assistance Program is a State funded program covering prescription drugs for individuals with limited resources who are not eligible for Medical Assistance. Coverage is limited to anti-infective drugs and maintenance drugs used to treat chronic conditions. A recipient copayment of \$5.00 per order is required.

Cost Basis:	EAC (WAC+10%) or IDC List
Dispensing Fee:	Lower of U/C or \$4.94 if cost is < \$47.83 \$6.17 if cost is > \$47.83
Method of Billing:	On-line
Dependent Age:	By individual card
Refills Allowed:	2 (maximum)
Generics Required:	Yes, see IDC List.
Doctor List:	No
Pre-Authorization:	>\$400 or >\$100 for 34 or greater days supply
Days Supply:	34 days supply, some 100 day supply allowed in up to a 100 days supply at one time.
Maintenance List:	No
Maryland Rx's Only:	No

#### **Special Items**

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	No
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, up to a 6 month supply
Diaphragms/Devices:	Yes
Insulin:	Yes, up to a 100 day supply
Syringes:	Yes
Diabetic Supplies:	Covered under DMS/DME Program
Injections:	Limited to nursing home or home administration.

## Metropolitan Life

Medimet Claims Office  
Oneida County Industrial Park  
Post Office Box 3018  
Utica, New York 13504-3020  
(315) 792-3882

Cost Basis:	AWP - 10%
Dispensing Fee:	\$3.20
Method of Billing:	UCF/tape/on-line
Dependent Age:	Most 19/25, some have no limit
Refills Allowed:	1 year or by law. Some groups have mandatory mail-order.
Generics Required:	Federal MAC list unless DAW
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Most have limits, varies by plan
Maintenance List:	Most plans have lists
Maryland Rx's Only:	Yes
Processor:	Medimet

### Special Items

Smoking Cessation:	Varies by plan
Rogaine:	Most plans do not cover
Retin A:	Pre-auth required if age over 26
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes for most plans
Rx Vitamins:	Yes
Anorectics:	Varies by plan
Contraceptives:	Varies by plan
Diaphragms/Devices:	Varies by plan
Insulin:	Yes
Syringes:	Yes, for most plans only
Diabetic Supplies:	No
Injections:	Varies by plan

*Notes:* Some programs have copays determined by price. For example, Sears has a \$10 copay for prescriptions costing less than \$75.00 with a \$15.00 copay for prescriptions greater than \$75.00.

## NPA

National Prescription Administrators  
1200 Route 46  
Clifton, New Jersey 07013  
(800) 882-6727 *Claims Submission*  
(800) 522-6727 *Questions on Claims*  
(800) 526-7813 *Pharmacy Questions*

Cost Basis:	AWP - 10% for most plans
Dispensing Fee:	Lower of U/C, fees vary
Method of Billing:	UCF/tape/on-line
Dependent Age:	Varies by group/plan
Refills Allowed:	Some plans allow only 6 months, others allow up to one year
Generics Required:	Some plans split copays, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Greater of 34 days supply or 100 doses for most plans
Maintenance List:	No
Maryland Rx's Only:	Varies by group/plan
Processor:	NPA

### Special Items

Smoking Cessation:	No for most group/plan
Rogaine:	No for most group/plan
Retin A:	Yes, only up to age 19
Cyclosporine:	Varies by group/plan
Retrovir:	Varies by group/plan
Fertility:	Varies by group/plan
Rx Vitamins:	Yes, for most group/plans
Anorectics:	No for most group/plans
Contraceptives:	Yes for plans 1,3
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Varies by group/plan
Diabetic Supplies:	Varies by group/plan
Injections:	Varies by group/plan

*Notes:* If a generic is required and patient requests brand, the patient must pay the difference. Brand name versions of generic drugs are allowed for D-group patients if the physician writes "brand medically necessary" on the prescription. NPA pays a \$1.00 compounding fee. Use AA0000000 if no DEA numbers has been assigned to a prescriber. For coverage and eligibility information, refer to the NPAS system response.

## NPP-PHS

Nationwide Prescription Plans  
 Prescription Health Systems/Caremark  
 6025 Slauson Avenue  
 Culver City, California 90230-6507  
 (800) 421-2342  
 (310) 391-1133  
 (310) 391-0171 FAX

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	UCF/tape/on-line
Dependent Age:	Varies by plan
Refills Allowed:	Varies by plan
Generics Required:	Most plans require
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	30 day supply, some plans allow the greater of 30 days or 100 doses.
Maintenance List:	Yes, for most plans
Maryland Rx's Only:	Yes
Processor:	PHS for its own NPP network

### Special Items

Smoking Cessation:	Varies by plan
Rogaine:	Varies by plan
Retin A:	Varies by plan
Cyclosporine:	Varies by plan
Retrovir:	Varies by plan
Fertility:	Varies by plan
Rx Vitamins:	Varies by plan
Anorectics:	Varies by plan
Contraceptives:	Varies by plan
Diaphragms/Devices:	Varies by plan
Insulin:	Varies by plan
Syringes:	Varies by plan
Diabetic Supplies:	Varies by plan
Injections:	Varies by plan

*Notes:* PHS NPP program pays once to twice monthly. Some plans have a maximum 21 day supply of medication; thereafter the patient must use Baxter's mail order program. Maryland pharmacies who use PHS for Blue Cross, Columbia FreeState, Care First, etc. are already included in the PHS NPP network. The point-of-sale program allows a 30 day window to "back-out" claims.

## PAID Prescriptions

PAID Prescriptions  
 Post Office Box 100  
 Fairlawn, New Jersey 07410-9900  
 (800) 922-7890  
 (800) 922-1557

Cost Basis:	Varies, many plans ACQ
Dispensing Fee:	Varies
Method of Billing:	UCF/tape/on-line
Dependent Age:	Most plans 19/23
Refills Allowed:	By law
Generics Required:	Many plans use FDA list, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Most 34 days supply. Some plans allow 100 doses.
Maintenance List:	No
Maryland Rx's Only:	Most plans
Processor:	PAID

### Special Items

Smoking Cessation:	No, for most plans
Rogaine:	No, for most plans
Retin A:	Some plans
Cyclosporine:	Some plans
Retrovir:	Some plans
Fertility:	Some plans
Rx Vitamins:	Some plans
Anorectics:	Some plans
Contraceptives:	Some plans
Diaphragms/Devices:	Only for a few plans
Insulin:	Yes, for most plans
Syringes:	Some plans
Diabetic Supplies:	Some plans
Injections:	Some plans

*Notes:* PAID provides a chart with plan rules. Many plans do not cover DESI drugs. The point-of-sale system allows 14 days to "back-out" claims.



## PCS

### General Information

PCS, Inc.  
Post Office Box 52115  
Phoenix, Arizona 85072-2115  
(602) 391-4717  
(800) 345-5413 *Recap Only*

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	On-line
Dependent Age:	RECAP verification
Refills Allowed:	Varies
Generics Required:	Some plans split copays, *PPD
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	Varies
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PCS

#### Special Items

Smoking Cessation:	Verify through RECAP
Rogaine:	No
Retin A:	Verify through RECAP
Cyclosporine:	Verify through RECAP
Retrovir:	Verify through RECAP
Fertility:	Verify through RECAP
Rx Vitamins:	Verify through RECAP
Anorectics:	Verify through RECAP
Contraceptives:	Verify through RECAP
Diaphragms/Devices:	No
Insulin:	Verify through RECAP
Syringes:	Verify through RECAP
Diabetic Supplies:	Verify through RECAP
Injections:	Verify through RECAP

*Notes:* Some groups have an annual deductible. Refer to "State Employees" section for details on PCS' program for the Maryland Department of Personnel. Under the Federal Employee Program, you must provide patient with captured reference number, bill U/C and accept that or plan limits.

## PCS

### Maryland State Employees

PCS, Inc.  
Post Office Box 52115  
Phoenix, Arizona 85072-2115  
(800) 345-5413 *RECAP only*  
(602) 391-4717

Cost Basis:	AWP-8%
Dispensing Fee:	\$3.75
Method of Billing:	On-line
Dependent Age:	RECAP Verification
Refills Allowed:	1 year
Generics Required:	State Formulary
Doctor List:	No
Pre-Authorization:	Some drugs, see formulary.
Days Supply:	34 days supply
Maintenance List:	Yes, up to 100 days supply
Maryland Rx's Only:	Yes
Processor:	PCS

#### Special Items

Smoking Cessation:	3 month supply/lifetime
Rogaine:	No
Retin A:	Pre-auth, for skin cancer only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Pre-authorization only
Rx Vitamins:	No
Anorectics:	Pre-auth for children with ADD only
Contraceptives:	Yes, up to a 6 month supply
Diaphragms/Devices:	Norplant only, pre-authorization
Insulin:	Yes, up to 4 vials
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

*Notes:* Copays will vary by brand/generic, formulary/non-formulary/Select or Non-Select pharmacy. DESI drugs are not covered. Growth hormones are permitted only on pre-authorization. Pre-authorization required for Rocaltrol, Norplant. Physician must obtain pre-authorization for progesterone suppositories during pregnancy.

## PDI

Prescription Drugs, Inc.  
1111 Cherry Hill Road  
Baltimore, Maryland 21225  
(410) 354-1466

Cost Basis:	AWP
Dispensing Fee:	\$ 2.75
Method of Billing:	On-line
Dependent Age:	19/23
Refills Allowed:	By law
Generics Required:	Yes for some plans. Some plans split copays.
Doctor List:	No
Pre-Authorization:	> \$200
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	PDI

### Special Items

Smoking Cessation:	Yes, for some plans only
Rogaine:	Yes
Retin A:	Yes, for acne only
Cyclosporine:	Pre-authorization required
Retrovir:	Pre-authorization required
Fertility:	Pre-authorization required
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Some plans up to 3 cycles. 1 copay per pack.
Diaphragms/Devices:	No
Insulin:	Yes, up to 3 vials
Syringes:	Yes, up to 30 with insulin only
Diabetic Supplies:	Some plans
Injections:	No

*Notes:* PDI did not respond to our 1993 survey. This information is reprinted from the 1992 directory.

## Penn Scripts

Penn Scripts  
508 North Third Street  
Harrisburg, Pennsylvania 17101  
(800) 544-6668

Cost Basis:	AWP
Dispensing Fee:	Lower of U/C or \$2.75 to \$3.25
Method of Billing:	On-line
Dependent Age:	Covered if name on card
Refills Allowed:	By law
Generics Required:	*PPD
Doctor List:	No
Pre-Authorization:	Yes, for some drugs
Days Supply:	Varies by plan
Maintenance List:	Varies by plan
Maryland Rx's Only:	Yes
Processor:	Penn Scripts

### Special Items

Smoking Cessation:	Varies by plan
Rogaine:	No
Retin A:	Varies by plan
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Varies by plan
Rx Vitamins:	Varies by plan
Anorectics:	Varies by plan
Contraceptives:	Varies by plan
Diaphragms/Devices:	No
Insulin:	Yes, AWP plus fee
Syringes:	Varies by plan
Diabetic Supplies:	No
Injections:	Varies by plan

*Notes:* There is a \$2,000/year maximum on some plans. There is no nursing home coverage. There is a 180 day limit for submitting claims. Penn Scripts requires the state license number of the prescriber on the claim form.

*The Right  
prescription for all  
pharmacy owners...*

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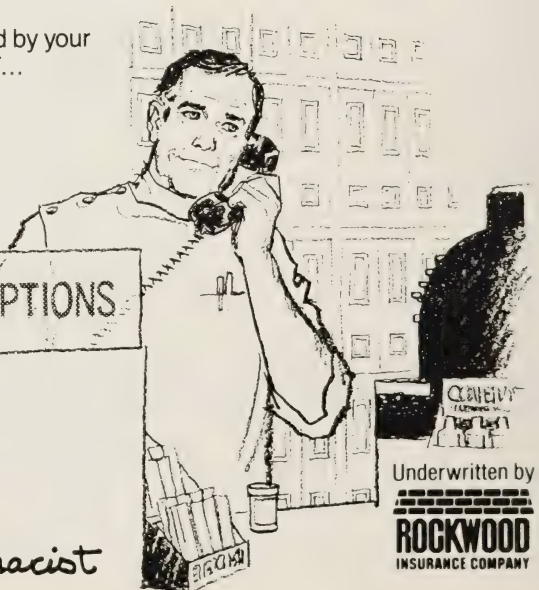
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## Surviving A Third-Party Audit

*Concluded from page 7*

However, there are times when the audit doesn't go smoothly and the third-party expects to be reimbursed for prescriptions that they believe were inappropriately paid by them to your pharmacy.

Some third-parties use an extrapolation method to determine whether they are due money from you. Their calculations, for example, would say that since you had errors or discrepancies on ten percent of the claims audited, ten percent of the total claims submitted and paid for by the third-party must also be in error. Under no circumstances should you accept this type of audit "blackmail."

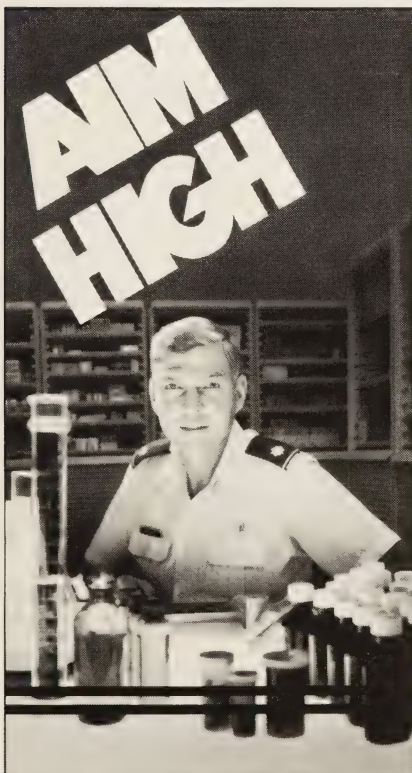
If you receive a report/bill for an amount based on audit extrapolated figures, you should refer to the notes you took during the audit. Did you have reasonable explanations for any

discrepancies on prescriptions or records? What was the auditor's response to your explanations at the time of the audit? Ask for, and if necessary, demand a complete listing from the third-party of prescriptions with discrepancies and exactly what they are.

Generally, a third-party is willing to negotiate some on what they believe you owe them. At this point, and especially if their claim against you is significant, you should contact your pharmacy's attorney for assistance. Don't make the mistake of some pharmacists and just send the third-party a check without first obtaining legal advice and exhausting the third-party's appeal process.

### Conclusions

Surviving a third-party audit can be relatively painless if you are properly prepared. Remember the basic rules: assert your right to have the audit conducted at a reasonable time that doesn't impose on your business nor on your patients, be honest with the auditor, never volunteer information, be familiar with Maryland's pharmacy laws and regulations, and never allow the auditor to have free access to your prescription files or records. And, if in doubt or if you need assistance, take advantage of the Maryland Pharmacists Association's resources and give us a call. **R**



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## Patient's Abortion Not Relevant Evidence

David B. Brushwood, J.D.



In January, 1989, a physician diagnosed a Minnesota woman as having a chlamydia infection. The physician prescribed doxycycline. A pharmacist mistakenly filled the prescription with a diuretic.

When the patient's infection did not respond to the medication, the physician ordered a refill. The pharmacist again incorrectly filled the prescription with a diuretic.

The patient's condition worsened and her physicians diagnosed her as having pelvic inflammatory disease, a potential result of untreated chlamydia. She was immediately admitted to the hospital for treatment and eventually surgery. On the last day of the patient's hospital stay, her physician discovered the pharmacist's error.

In 1990, the patient brought suit against the pharmacy where the misfilling had occurred, alleging that the misfilling caused her to become infertile. The pharmacy defendant admitted negligence, but claimed that its negligence was not the cause of the patient's infertility.

On September 20, 1991 a jury returned a verdict for the patient, awarding her \$489,843.85 in damages. The pharmacy appealed.

On appeal, the key issue was whether the trial court had erred by refusing to permit the jury to consider testimony concerning two elective abortions that the patient had undergone years earlier. The pharmacy contended that the patient had testified that she "always wanted to have children," and that the evidence of her abortions would refute her statement. But the appellate court noted that the patient had really said she dreamed of "having a house, a husband, and children," which implies she always wanted children when the time was right. An abortion at one time of life does not indicate lack of interest in motherhood at a more propitious time.

The verdict against the pharmacy was upheld. This is one more example of a case that could have been prevented by patient counseling. **R**

Based on: *Olson v. Walgreen Company*, 1992 Westlaw 322054 (Minn. App. November 10, 1992)

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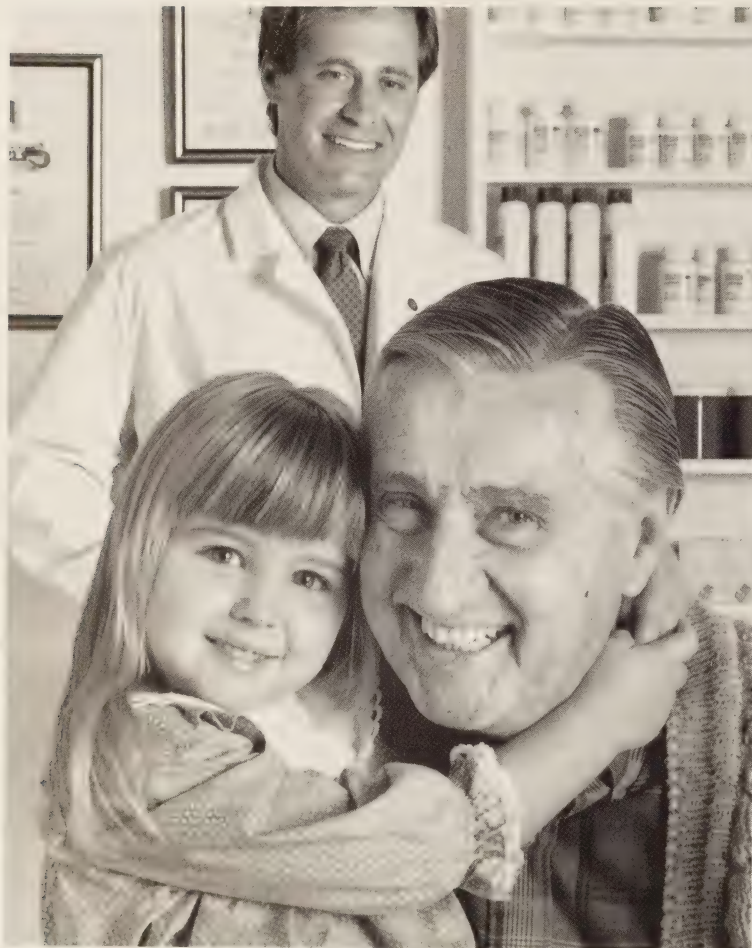
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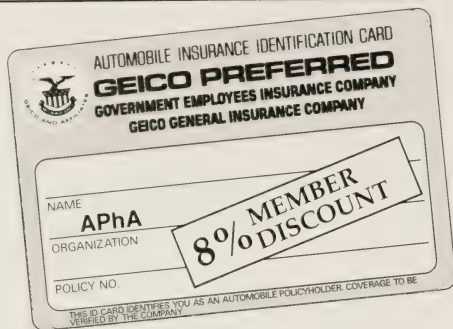
VOL. 69

APRIL, 1993

NO. 4



*Pharmacy's Role in  
National Health Care Reform*



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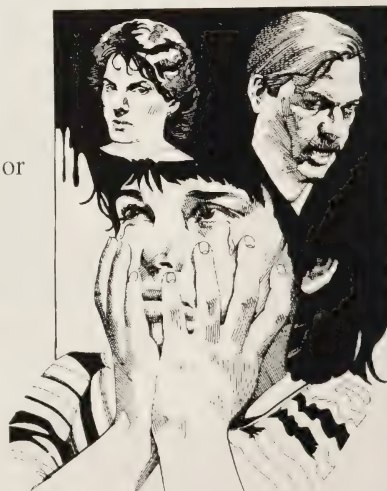
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# The Maryland Pharmacist

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650 West Lombard Street, Baltimore, Maryland 21201-1572

April 1993

Volume 69

Number 4

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## National Health Care Reform

David G. Miller, P.D., Executive Director, MPhA



In the February 1993 issue of *The Maryland Pharmacist*, MPhA President Nicholas Lykos's commentary asked for one national pharmacy voice to advance the profession's needs and wants in the national health care reform process. Since then, MPhA's Board of Trustees has been actively reviewing various reform position statements from the American Pharmaceutical Association, NARD, the National Association of Chain Drug Stores, the Academy of Managed Care Pharmacy, and the Pharmaceutical Manufacturers Association. In addition, a delegation from MPhA's Legislative Committee met with Congressman Ben Cardin to discuss how MPhA could assist him in his development of a new health care program.

In his commentary, Dr. Lykos stated:

Pharmacy and drug expenditures are not a *major factor* in the costs of health care. Given that fact, I am concerned that the national organizations might just be missing the point. To our elected officials, pharmacy is almost an afterthought. Yet, we in pharmacy, somewhat full of our own self-importance, are putting forth two heavily researched tomes to those officials.

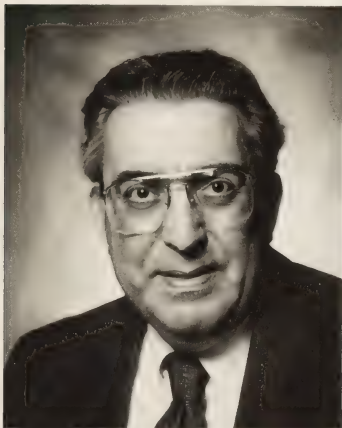
This issue of *The Maryland Pharmacist* contains copies of all the national pharmacy organizations' health care reform policy statements that have been shared with your Association. Many pharmacy groups have said that the health care reform process is a "generational opportunity" for pharmacy to effect positive change for the profession's future.

As you can see from these position papers, many of the ideas are common to the various organizations. Even within diversity there is similarity.

Ultimately, pharmacy must unite together with one single voice and one clear message. Regardless of how strongly one organization may promote parts of that message over another, our opportunity to effect a substantial change for the betterment of pharmacy depends on our national associations' ability to work together to convey pharmacy's needs. **R**

## President's Commentary

Nicholas C. Lykos, P.D., President



The article facing my commentary in the January issue of *The Maryland Pharmacist* reported that, once again, pharmacists are at the top of the Gallup Poll when it comes to the trust of the American public. But who or what can the pharmacist trust? One thing is for sure, pharmacists can no longer trust their own memory when it comes to recommending over-the-counter products to our patients?

What? Not trust our own professional judgement? Why, pharmacists are the drug experts! No one is more knowledgeable or skilled in selecting the right OTC for a patient than a pharmacist.

If that's your response, consider what I call label masquerading....

In six months, A.H. Robins' Dimetane will no longer exist. But if you look very closely at the labeling of the "new" Dimetapp Allergy, guess what you'll find? Sure enough, there's Dimetane. Actifed Sinus contains none of the ingredients found in Actifed. Dramamine II is a copy of Pfizer's Marezine and is being marketed by Upjohn along with the old Searle Diphenhydramine by Searle. OTC Anusol no longer contains the perabalsam that was part of the prescription formulation. There is neither kaolin nor pectin in new formulations of Kaopectate -- it's loperamide. There is no Excedrin in Excedrin PM-IB. Contact originally was an OTC formulation of Ornade. Now both of these products have undergone changes.

And let's not forget Bayer! Since before World War I, Bayer has meant "aspirin" to both pharmacists and consumers. Take a close look at the new Bayer Select family.... it's aspirin-free. Same thing with the classic combination of aspirin and caffeine in Anacin. Now we have Anacin-Free, which I guess is rather like Caffeine Free Diet Coke, as it has neither aspirin and nor caffeine!

Where did all of this label masquerading start? In the pharmaceutical industry, I believe it can be directly traced to Wyeth's concerted efforts in the early 1980's to expand the market share of their Phenergan family of cough products. One of the products was prominently labeled "Phenergan with Codeine" and a sister product was "Phenergan without Codeine". The latter had neither a codeine derivative (as indicated on the label) nor dextromethorphan nor any cough suppressant. The prominence of the words "Phenergan" and "Codeine" on both products created a great deal of confusion for pharmacists. In my pharmacy, we highlighted the "without" to remind us to be especially careful in what we were dispensing. This negative labeling was eventually changed by Wyeth.

The OTC industry is highly competitive; both small and large firms seek to gain shelf-space and exposure to the consumer. It makes sense, from a marketing standpoint, to capitalize on a recognized brand-name by applying that brand-name to as many derivatives as possible. Think about the shelf space devoted in your local grocery store to cola products. The new clear colas are using their brand names to obtain more exposure to the buying public.

*Concluded on page 7....*

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Perhaps the marketing strategy of "label masquerading" can work to pharmacy's advantage. Perhaps this kind of intentional consumer confusion can be used to justify the establishment of a third-class of drugs subject to the pharmacist's and only the pharmacist's control.

American pharmacy has been debating a pharmacist-only class of drugs for several years. We are the only major industrialized nation that allows the sale of OTCs in "quickie marts" or gas stations instead of pharmacies. The opposition from the Non-Prescription Drug Manufacturers Association to such an idea is strong.

Until there is a pharmacist-only class of drugs, I suggest that in your practice....

- a pharmacist should be available at all times to review OTC purchases and counsel about the product.
- place the above listed (and the many other) OTC products suffering from the label masquerading identity crisis *behind* the counter to foster dialogue between the purchaser and the pharmacist.
- begin working in your practice to educate consumers about the role of the pharmacist in ensuring proper use of OTC medicines as well as prescription drugs.

A third-class of drugs will only be successful if it is expected and accepted by the public. Do your part today to start making pharmacists class of drugs a reality.

And, look closely at those OTC labels!

R

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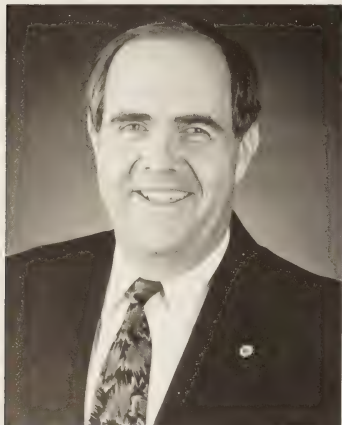
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# A Year of Decision in Health Care Reform

John A. Gans, Pharm.D., Executive Vice President, American Pharmaceutical Association



Pharmaceuticals and the services provided by pharmacists are among the most cost effective methods of health care available. Medications are indispensable in preventing and treating illnesses. The pharmacist's responsibility in counseling patients and using the knowledge of pharmaceutical science to assure selection of appropriate therapy adds significant value to the prescription product. There is evidence, however, that the public is not fully realizing the full potential benefit from these resources. It is imperative that professional pharmacy services as expressed by the concept of "pharmaceutical care" be recognized as a solution to the two most critical problems in drug use management: cost and sub-optimal therapeutic outcomes. In recent years pharmaceutical care has become a more integral part of our health care system. Public policy makers, employee benefit managers, insurers, and medical professional organizations need to better understand this important trend and the benefits it provides.

## What's Right and Wrong

While physicians and pharmacists have served patients for more than 3,000 years, it has only been in this century that the care provided by these professionals has achieved such significant and dramatic advances in preventing, treating and curing illnesses and in improving the quality of life. A primary vehicle for this change has been a pharmaceutical revolution that started with antibiotics and the sulfa drugs and continues today with wonder drugs based on microbiology and biotechnology.

Prescription medicines successfully

treat major acute and chronic diseases, prevent unnecessary physicians' visits, hospitalizations, surgeries and long-term institutional care and ease pain and provide symptomatic relief. When properly used, they save far more than the seven percent of health care costs and 1/2 percent of the GNP that they cost. However, many individuals do not have insurance coverage for outpatient drug therapy and often face a financial burden in assuring that their medication needs are met.

Although medication use has assumed a primary role in health care, its provision is often uncoordinated and highly fragmented. One result is that medication related problems impact about two percent of the 1.6 billion prescriptions that are written and filled each year. It has been estimated that \$36 billion could be saved annually by improving patient compliance, reducing inappropriate drug use and medication-induced illnesses and hospitalizations, and decreasing preventable adverse effects and interactions. This represents about four percent of America's health care bill that could be saved through pharmaceutical care.

## Remedying These Wrongs

The pharmacist has an important role to plan in helping society deal with the costs of pharmaceuticals and assuring appropriate patient outcomes through patient counseling and drug therapy management. To do so, pharmacists must be allowed to move away from their traditional role which saw them primarily as dispensers of drug products and into their rightful position as a full-fledged partner with patients and prescribers in the provi-

sion of primary health care services. Many pharmacists are already working effectively with these new responsibilities. The professional services which define this new role are called "pharmaceutical care," although they have sometimes been called "patient-oriented pharmacy practice" or "clinical pharmacy."

Pharmaceutical care is a proven approach to dealing with medication costs and promoting quality therapeutic outcomes. Not only does it rest on a growing body of research that says it works, but it has the advantage of utilizing an existing and well-prepared resource, the pharmacist. As a group, pharmacists are among the most highly trained of all health professionals and are the single most knowledgeable source on the use of pharmaceutical products. And, pharmacists are the most accessible health care professionals for meeting patient health and medication information needs.

The elements of pharmaceutical care can be defined as follows:

- meaningful interaction among patient, physician, and pharmacist about prescribed medications and their proper use, including patient counseling and consultation between the physician and pharmacist, and
- the collection of patient information and the undertaking of drug utilization review to: identify potential and actual drug-related problems, to resolve or prevent their occurrence, to identify opportunities to achieve similar therapeutic results with less expensive medications.

- Pharmaceutical care acknowledges that the responsibility of the pharmacist is not limited to dispensing of a commodity and extends beyond that point in time when the prescription order is filled.

Pharmaceutical care contemplates ongoing drug therapy management with a continuum of services provided by the pharmacist, in collaboration with other health professionals, which will achieve the desired therapeutic outcome and improve the patient's response to medications and quality of life. More cost effective health care service utilization should be a result of improved drug therapy management.

Among the specific activities pharmacists would perform are:

- participating in the drug selection process and selecting therapeutic objectives
- selecting the drug product dosage form and source of supply, determining the dose and dosage schedule, and preparing the drug product for patient use.
- providing the drug product to the patient along with appropriate drug information; and
- monitoring the patient to maximize compliance and detect adverse drug reactions and interactions.

To some extent, pharmaceutical care is delivered in every pharmacy in America right now. Yet, its full potential is unrealized. The objective,

however, is clear. Pharmacists should have a professional, caring relationship with every patient to whom they provide any component of pharmaceutical care. The patient should be viewed as a partner in the process of providing that care. Pharmacists must accept increased professional responsibility for assuring optimal therapeutic outcomes for their patients through the provision of pharmaceutical care.

#### **Why Not Pharmaceutical Care Now?**

As pharmacists work with public and private health care purchasers and with medical groups to expand the availability of pharmaceutical care, there are barriers that have impeded this progress and will need to be addressed. Federal legislators have already involved themselves in the need to break down these barriers through the enactment of OBRA-90 provisions that require: mandatory drug use review and patient counseling for Medicaid patients; and government-sponsored demonstration projects relating to the provision of clinical pharmacy services. Nonetheless, more will need to be done to make pharmaceutical care widely available.

Pharmacists are not adequately integrated into the system. To provide pharmaceutical care to patients requires a more effective integration of the pharmacist's practice with other components of the health care system. Essential information needed to provide comprehensive pharmaceutical care, i.e. diagnostic and laboratory data, care plans of other providers, historical information, and patient interview data, must be incorporated into the pharmacist's practice by



building relationships with other members of the health care team. In doing so, pharmacists must restructure their activities to utilize the full range of technology, information systems, and supportive personnel necessary for the delivery of pharmaceutical care. Health care purchasers must insist that such systems become available so that quality and savings outcomes can be achieved.

Professional empowerment issues need to be resolved. The power of pharmaceutical products is not fully unlocked by a physician handing a prescription to a patient. However, the "value-added" provided by pharmaceutical care is often blocked by formal and informal restraints on the pharmacist's role. The resolution of this lies in: development of collaborative practice with physicians; and expanding pharmacists' access to medical information systems. Also, states should seriously consider the revised Model Pharmacy Practice Act developed by the National Association of Boards of Pharmacy. The revised model act includes a number of statutory provisions that would facilitate the provision of pharmaceutical care.

Reform of the payment system is also needed. The HHS Inspector General's 1990 report summed this up well: "one of the most formidable barriers facing pharmacists... is the transaction-based reimbursement structure of [pharmacy]. The result typically is a focus on product and price rather than provision of clinical services for which there is no incentive."

The pharmacy profession is working hard to develop and implement models of reimbursement that will stimulate the cost of quality benefits

of pharmaceutical care. Increasingly, the purchasers of care, both public and private, must share in this effort if the patient is to benefit.

The following details the four policies presented by APhA, ASCP, and ASHP at a briefing to the White House Task Force on National Health Reform that was held on March 5, 1993.

### **Pharmaceuticals and Pharmaceutical Care as a Core Benefit**

#### *Position*

Pharmaceutical products and pharmaceutical care (pharmacists' services) should be included as a core benefit in a reformed health care system.

#### *Rationale and Impact*

Access to pharmaceuticals and pharmaceutical care is a necessary component of any health care reform proposal that strives to control costs and provide quality care. Appropriately managed pharmaceutical therapy improves patients' quality of life and lowers overall health care expendi-

### **Pharmacy and Health Care Reform Policy Positions**

1. Pharmaceutical products and pharmaceutical care (pharmacists' services) should be a core benefit under health care reform.
2. Pharmacists' services and the proper management of medications can generate significant savings to a reformed health care system.
3. Quality assurance programs administered by pharmacists can significantly improve the effectiveness of medications in achieving positive patient outcomes.
4. Integrated information systems that include pharmacists offer the potential for cost savings and better patient outcomes.

tures by reducing the need for more costly services (e.g. hospitalizations, long term care, surgery).

#### *Discussion*

Medications are used to successfully diagnose, prevent, and treat major acute and chronic illnesses and slow or halt the progression of more serious conditions. Although prescription medications represent only seven to 10 percent of the total health care dollar, when utilized properly, their financial impact is far more significant.

Patients often fail to gain optimal effectiveness from pharmaceuticals under the current system because of a lack of access and, in some cases, poorly coordinated care. Also, a higher portion of prescription costs are borne out-of-pocket by consumers in comparison with other health care services. This results in access problems for those without adequate insurance coverage. In addition, the U.S. spends enormous sums of money on medicines that are used inappropriately or to treat illnesses that result from the inappropriate use of medi-

cines, including unneeded drugs prescribed for an illness, the wrong use of correct drugs, wrong doses and dosing schedules, lack of compliance with appropriate therapy, and blind compliance with inappropriate therapy.

A pharmaceutical benefit in a reformed health care system should acknowledge that patients have differentiated needs for pharmaceutical products and services. Pharmacists, in collaboration with physicians, patients and other providers of health care services, can work to manage and improve the drug-use process and maximize therapeutic outcomes in patients according to their individual needs for care. An effective pharmaceutical care program with appropriate competitive incentives for providers is a reasonable and cost-effective component of a reformed health care delivery system.

### **Managing the Economics of Pharmaceuticals and Pharmaceutical Care**

#### *Position*

Pharmacists' services and the proper management of medications can generate significant savings to a reformed health care system.

#### *Rationale and Impact*

Medications and pharmaceutical care offer an accessible and cost-effective method for treating disease, but only when properly used. The current system lacks incentives and presents obstacles to optimal patient outcomes. The goals of economic reform for pharmaceutical products and pharmacists' services are to: 1) maximize the return on the investment made in expenditures for medications; 2)

increase market-based competition in the industry while eliminating cost-shifting between market segments; and 3) alter the incentives for patients and providers to improve drug therapy outcomes. Enhanced systems of cost control and changed models of payment for services could yield considerable savings and marked improvements in patient care at a reasonable cost to payers.

#### *Discussion*

Over the last ten years the cost of pharmaceuticals have increased at an annual rate of approximately 10 percent, a rate much higher than the annual increases in the consumer price index. Price controls on pharmaceuticals may reduce expenditures or slow the escalation in the cost of drugs in the short-term, but such an approach may have negative consequences on other costs of care and long-term improvements in the prevention and cure of disease. Competitive market forces should be enhanced in order to moderate the costs of this component of the medical care system and should increase quality performance by providers.

Pricing practices of manufacturers and insurers and other payers should reward quality providers, efficient purchasers and economies of scale. Anti-competitive marketing practices which arbitrarily shift costs from one market segment to another should be eliminated. This will insure consistent consumer access to the valuable primary health care services of pharmacists at an affordable cost.

Because a significant amount of money is spent each year for unnecessary drugs and the cost of treating illnesses induced by inappropriately managed therapy, pharmacists are prepared to partner with prescribers and patients to improve medication use in America. The transaction-based reimbursement system currently used for out-patient prescription coverage discourages this approach and must therefore be revamped. An alternative system, which includes incentives for patients and providers to use medications more prudently and for pharmacists to manage the costs of therapy, must be introduced.

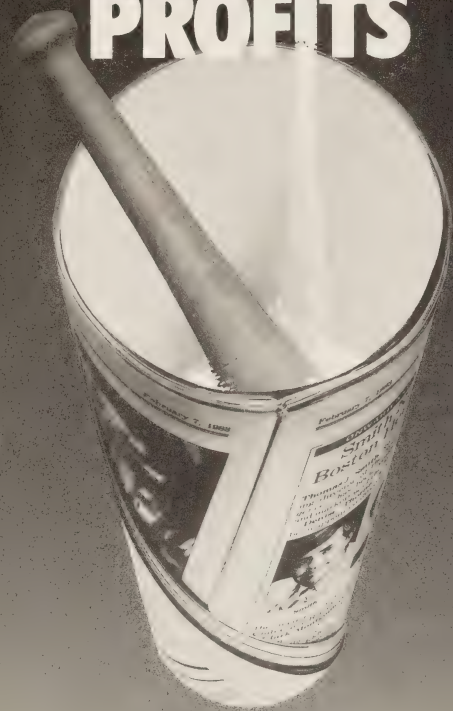
Such a system empowers pharmacists to: identify the most cost effective drug product which will achieve

#### ***Pharmacy Organizations Presenting These Policy Positions***

American Pharmaceutical Association  
American Society of Consultant Pharmacists  
American Society of Hospital Pharmacists  
American Association of Colleges of Pharmacy  
American College of Clinical Pharmacy  
National Association of Boards of Pharmacy  
National Pharmaceutical Association  
and

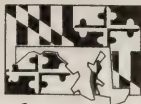
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the intended therapeutic outcome for the patient; insure that the drug regimen is properly selected; and manage the full course of therapy (e.g. patient education and monitoring). Efficient systems for documenting and paying for such services are currently being tested.

### **Quality Assurance in the Use of Medications and Pharmacy Services**

#### *Position*

Quality assurance programs administered by pharmacists can significantly improve the effectiveness of medications in achieving positive patient outcomes.

#### *Rationale and Impact*

Delivering quality pharmaceuticals and pharmacy services is beneficial in a health care benefit program for two basic reasons. First, emphasizing a quality oriented approach eliminates errors and the additional costs of having to correct drug use problems. Second, providing quality service increases patient and provider satisfaction with the health care benefit program which in turn has a positive effect on patient health outcomes and quality of life.

#### *Discussion*

Quality assessment and assurance programs and the use of quality management techniques must be incorporated into a medication and pharmaceutical care benefit program to increase quality and decrease the costs of care. Quality assessment and assurance programs related to individual patient care should be implemented at local levels through the collaborative efforts of health-care practition-

ers rather than through centralized systems which cannot address unique patient or provider issues.

Examples of quality assessment and assurance procedures for medication use include drug utilization review, formulary systems, therapeutic drug monitoring by pharmacists and pre-authorized product interchange. Increase patient education and monitoring by pharmacists and the use of patient outcomes analyses are also integral pieces of a quality oriented medication benefit program. Increasingly sophisticated medications and technologies may also suggest the need for a reexamination of the classification system for drugs.

All pharmacists should be allowed to participate in patient care networks based on adherence to quality performance standards. Incentives for patients and providers should be built into the network to insure that quality standards are maintained. Professionals who provide direct patient care should be involved in the design and implementation of the quality improvement techniques used in a program.

Moreover, quality oriented programs must recognize local variations in epidemiology, demography, and practice standards and most importantly information related to quality assessment and assurance activities must be held in confidence by all parties.

### **Integrated Information Strategies**

#### *Position*

Integrated information systems that include pharmacists offer the potential for cost savings and better patient outcomes.

#### *Rationale and Impact*

Integrated information systems that include pharmacists are needed to facilitate the delivery of efficient, high quality care. Current systems lack integration and limit effective communication of information between providers. Better patient-specific information exchange and more efficient claims/administrative management systems will decrease costs, improve the quality of care, and improve patient understanding of the care they are receiving. This must be achieved with adequate protection for patient confidentiality.

#### *Discussion*

Provision of higher quality, more efficient pharmaceutical care requires a more effective integration of pharmaceutical care with other components of the health care system. Current legislative and regulatory mandates require pharmacists to review the appropriateness of patients' drug therapy and provide patient counseling services to improve outcomes of drug use. To meet this obligation, pharmacists must have access to pertinent patient-specific information, including: appropriate demographic information and medical history; relevant diagnostic and laboratory data; statement of therapeutic goals or desired outcomes; list of actual or potential drug-related problems; and other therapeutic or clinical monitoring parameters. In addition, the pharmacist must document recommendations on potential therapeutic options and systematically record the services provided.

Many health care providers, particularly in ambulatory care settings, deliver services to patients in isolation from others caring for the same

individual. This practice leads to fragmented, duplicative and, in some cases, poor quality care. An integrated information strategy will promote efficiency and increase the quality of care.

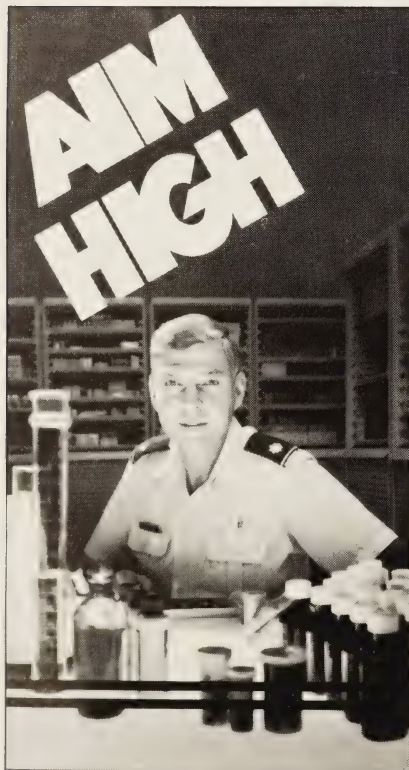
Information exchange is also an essential component of efficient administrative (i.e. claim processing) systems. Current health care delivery systems suffer from redundant and non-standardized administration with unnecessary layers of intermediaries in claims management systems. Uniform standards for pharmaceutical care information and claims administration systems should be established which utilize electronic technologies and eliminate inefficient layers of administration. Uniform systems would increase quality assurance capabilities and ease exchange of patient-specific information between providers. R

## Managed Care's Position

*Continued from page 24*

value of healthy lifestyles and preventive measures. They will recognize the value and limitations of health care services and participate in individual decisions concerning health care resources. AMCP believes that the mechanism for achieving this recognition and understanding is education. Adverse drug reactions and therapeutic failures will be minimized and optimal outcomes will be achieved through educated patients. It is AMCP's position that successful health care reform should include provisions for education our citizens concerning these issues in order to facilitate individual and personal responsibility.

The United States is entering an era of health care reform and will review and address a variety of proposals. The Academy of Managed Care Pharmacy feels strongly that the elements discussed above are important and essential and should be included as components of any effective solution. Representatives of the Academy are available to discuss these concepts and their success as requested. R



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# Independent Retail Pharmacy and Health Reform

*A Pro-competitive Agenda for the Pharmaceutical Marketplace*

Charles M. West, P.D. Executive Vice President, NARD



Health care reform has moved to the forefront of the concerns commanding the attention of the nation's policy makers. More than 30 legislative proposals were introduced in the last Congress addressing the need for change in the way health care services are delivered and paid for, and several states have either already taken or are considering action on health reform in the near future.

With some manner of reform clearly in the offing, NARD, the national association representing the nation's nearly 40,000 independent retail pharmacies, has been engaged in a more than year-long assessment intended to ensure that the provision of high-quality pharmacy services by independent pharmacists is guaranteed in our evolving health care system.

The association held seven regional Town Hall Meetings across the United States throughout the spring of 1992 to gather the views of the nation's independent pharmacists on health care reform. NARD's May 1992 Legislative Conference in Washington, D.C., targeted national health reform, and a symposium was held on the subject at NARD's October 1992 Annual Convention. The NARD House of Delegates also considered and adopted a resolution addressing health reform at the October convention.

Over the past year the association also brought in several outside experts to help NARD analyze the evolution of public and private health insurance coverage for pharmacy services in the United States. The objective of this analysis was to identify the incentives

and disincentives now controlling the provision of pharmacy services in third-party programs and to search for ways to modify those incentives to ensure that the highest levels of pharmaceutical care are available to all Americans receiving health care coverage.

Numerous studies have documented that pharmacy services are among the most cost-effective forms of health care, but the public is not currently realizing the full potential benefit from these services. Illnesses related to improper medication use by consumers are costing the U.S. health care system billions of dollars per year in patient morbidity and mortality. But to ensure high-quality, cost-effective pharmacy care, the U.S. health care system must be structured in such a way as to facilitate and take full advantage of pharmacists' well-documented expertise.

Pharmacy care, unlike other segments of the health care system, has traditionally been highly competitive. The average net profit after taxes of independent retail pharmacies nationwide has remained in the 3 percent range for more than a decade -- lower than the net profits of comparable small businesses outside the health care marketplace. True health reform should seek to capitalize fully on the competitive forces already at work in the retail pharmacy sector. The experiments of the last decade with so-called managed care have failed to do so, however, spawning instead numerous barriers to fair competition in the retail pharmacy marketplace.



The anticompetitive barriers include:

- Multi-tier pricing of pharmaceutical products by pharmaceutical manufacturers to different purchasers in the retail marketplace
- The refusal by pharmaceutical manufacturers to provide equal access to economies of scale to independent pharmacy buying groups
- Restrictions on the freedom of consumers to patronize the pharmacy or pharmacist of their choice
- Restrictions, through limited or closed provider networks, on the ability of independent pharmacists to provide services to patients in third-party prescription drug programs

Equal access by independent pharmacies to prices fosters competition; equal access by consumers to the pharmacy of their choice fosters competition; equal access by providers to third-party prescription drug programs fosters competition. If health care reform is to be truly based on managed competition, then equal access must be a centerpiece of that reform in the pharmaceutical marketplace.

Implicit, of course, in all of the discussions of health reform is the need to ensure cost containment. Equal access promoted cost containment. But throughout the 1980s, federal cost containment efforts in third-party

pharmaceutical programs were concentrated on reducing the reimbursement paid to pharmacists participating in such programs, limiting the number of pharmacies allowed to provide services in these programs, and, through various other means, restricting the availability of high-quality pharmacy services to consumers.

However, culminating with the passage of the Medicaid equal access law in 1990, we are now witnessing a transformation in the way policy makers and, increasingly, private insurers view pharmaceutical cost containment. The passage of the 1990 Medicaid "best price" provisions, coupled with the establishment of a four-year moratorium on pharmacists' reimbursement cuts, signaled a recognition by Congress that pharmacists should no longer be expected to bear the brunt of pharmaceutical cost containment and that primary responsibility for the continuing escalation of pharmaceutical costs rests not with the retail sector, but with rising prices at the manufacturer level.

As reported at NARD's annual convention in 1992: "The 1990 Medicaid equal access law stands as a landmark achievement. It has succeeded in redirecting the entire focus of the pharmaceutical cost containment debate, and it has exposed in excruciating detail the width and depth of discriminatory pricing in our industry."

NARD has developed three documents which represent the outcome to date of the association's assessment and recommendations for reform in the provision of and payment for

pharmacy services in the United States.

- *Principles for Maximizing Pharmacy Services for the American Public* offers general guidelines to policy makers as they consider health care reform.
- *The 1992 NARD Town Hall Meeting Recommendations on Nation Health Reform* identify the three primary points on which consensus was achieved among the independent pharmacists participating in the regional Town Hall meetings.
- *Federal Incentives for Cost Containment Through Consumer Access to Professional Pharmacy Services* was endorsed as policy by the NARD House of Delegates at the October 1992 Annual Convention.

A significant component of all three position documents is NARD's restatement of its long-standing commitment to ensuring that all consumers have the freedom to patronize the pharmacy of their choice. For the past several years, NARD has worked closely with several state pharmacy associations and consumer groups to enact pharmacy freedom of choice laws at the state level. That commitment is clearly restated in the positions described below.

Significantly, consumer access to the provider of one's choice is a key provision of the Democratic platform that will be guiding the Clinton-Gore

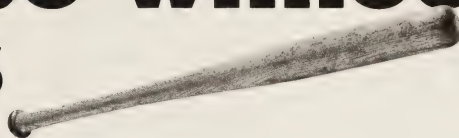
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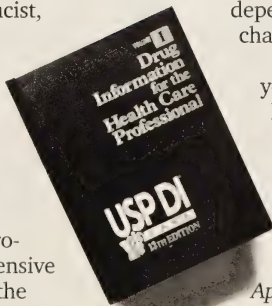


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administration's activities in the health arena, as well as an essential component of the 1991 health reform initiative developed by the influential Democratic Leadership Council when Governor Clinton was the DLC's chairman.

All of the positions have been forwarded to the various members of the Clinton-Gore transition team. NARD is looking forward to working closely with both federal and state officials to bring to pass legitimate health care reform that recognizes the important contributions the nation's independent pharmacists are able to make in our country's changing health care system.

R

### **Principles for Maximizing Pharmacy Services for the American Public**

**Principle I** -- All U.S. citizens must be able to select their provider of pharmacy services.

**Principle II** -- To maximize the quality of care that pharmacists provide to patients, the U.S. health care system must provide appropriate compensation to pharmacists for their professional services.

**Principle III** -- Patients differ in their needs for pharmacy services. Compensation for pharmacy services must include a recognition of the different levels of intensity and scope of the services pharmacists provide to meet the individual needs of their patients.

**Principle IV** -- Pharmacists must be enabled and encouraged to use the full range of their professional expertise in making medication-related decisions. Our health care system must not dictate specific pharmacy services or therapies that limit the use of the pharmacist's professional judgement or discretion and thereby undermine the value of the pharmacy services patients receive.

**Principle V** -- Pharmacists must have access to all relevant patient information to support their professional judgements and related activities.

**Principle VI** -- To ensure proper coordination of patients' medication therapies, the U.S. health care system must be designed to encourage and facilitate communication among pharmacists and other health care providers.

**Principle VII** -- Quality assurance programs related to individual patient care must be designed and implemented at local levels through the collaborative efforts of consumers, pharmacists, and other health care practitioners, and not through centralized bureaucracies.

**Principle VIII** -- Ongoing research, such as demonstration projects and evaluation studies, on the delivery of pharmacy services must be fostered and implemented to ensure that patients continue to receive optimal pharmacy services.

**Principle IX** -- The U.S. health care system must safeguard patient confidentiality in order to promote an uninhibited exchange of pertinent information from the patient to the pharmacist for the purpose of achieving optimal pharmacy services.

**Principle X** -- The U.S. health care system must respect the rights of each patient by adopting the NARD proposed **Patient Bill of Rights**.



## NARD's Patient Bill of Rights

### Rights Related to Choice of Provider

The pharmacy patient has the right:

- To seek a qualified and competent provider
- To choose from among the wide variety of providers available in the marketplace
- To receive definitive information regarding available services, so as to make an informed choice of provider

### Rights Related to Choice of Product

The pharmacy patient has the right:

- To receive any legally prescribed product, realizing this may require the patient to bear the expense of such a choice
- To ask for and receive any supplier's product that will legally fill a generically written prescription
- To know the supplier of any product received
- To have knowledge of alternative dosage forms available and to request an alternative from the physician

### Rights Related to Pharmacy Services

The pharmacy patient has the right:

- To direct, one-to-one access to the pharmacist
- To receive from the pharmacist information, instructions, and services regarding the safety and cost-effectiveness of drug therapy. This includes the right to information pertinent to product selection when allowed
- To expect the pharmacist to maintain a patient medication

## 1992 NARD Town Hall Meeting Recommendations On National Health Reform

The three primary recommendations below emerged from seven regional Town Hall Meetings NARD held across the country for independent pharmacists in the spring of 1992.

### Outpatient Prescription Drug Coverage

If there is national health reform, the nation's independent pharmacists want outpatient prescription drugs to be covered under such a program.

### Payment for Pharmacy Services

The nation's independent pharmacists want fair payment for participating in any outpatient prescription drug program. This means, at minimum, either marketplace pricing or another fair methodology that ensures the pharmacist full payment for the cost of the product, a mark-up to cover business operating expenses and provide a return on investment, plus a reasonable fee for the pharmacist's professional services. Additional fees should also be established for a wide variety of other professional interventions by the pharmacist with the prescribed drug therapy.

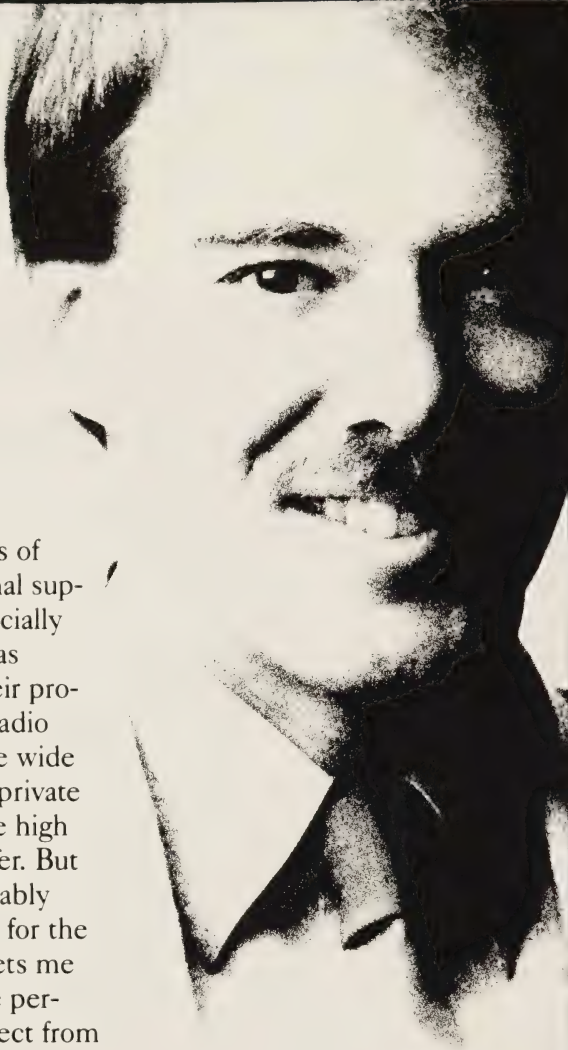
### Equal Access

Consumers must have the freedom to patronize the pharmacy of their choice in any health reform initiative. Accordingly, pharmacists must be guaranteed equal access to provide professional pharmacy services in any health reform program

record to promote good drug therapy

- To receive courteous service
- To clearly posted information on services available and on hours of service, including information on after-hours emergency service and how to obtain it
- To expect the pharmacist to be a public source of drug information
- To receive continuity of pharmacy services, for example, in the course of discharge from an acute care or extended care facility to the community
- To confidentiality in the handling of personal as well as drug and other health-related information
- To participate in one's own health care decisions, including the right to remain uninformed about drug therapy, unless others are thereby endangered.

R



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## Community Retail Pharmacy Coalition Statement

*Charles M. West, P.D. Executive Vice President, NARD*

*Ronald L. Ziegler, President & Chief Executive Officers, NACDS*



NARD, the national association representing independent retail pharmacy and the National Association of Chain Drug Stores (NACDS), have formed a Health Care Reform Coalition to forward the needs and value of the community retail pharmacist and pharmacy. On February 11, 1993 the Coalition issued a statement announcing these two organizations' commitment to the following fundamental concepts necessary to any reform of current health care delivery systems:

1. The provision of pharmacists' services are essential to any basic health care plan. As the most accessible health care professionals, our pharmacists are in a key position to ensure improved and appropriate medication use through an outpatient pharmacy benefit utilizing the current drug store infrastructure, resulting in decreased overall health care costs.
2. Current health care delivery systems suffer from redundant and non-standardized administration. Often, unnecessary layers of intermediaries are involved in claims management systems. Uniform standards should be established for the management of health care which utilize electronic claims systems and eliminate unnecessary administrative layers.
3. Ensuring the public's free access to community pharmacy and community pharmacy's free access to the marketplace are the best ways to provide pharmacists' services and preserve the competitive market which exists for the provision of those services.
4. Essential to the preservation of a competitive community pharmacy marketplace is the elimination of discriminatory pricing practices by manufacturers of prescription products. All pharmacies, irrespective of practice setting, must be able to acquire prescription drugs at the same price, subject only to economics of scale, including volume. **R**

# Managed Care and Health Care Reform

*Position Statement of the Academy of Managed Care Pharmacy*

*William N. Tindall, R.Ph., Ph.D., Executive Director, AMCP*



The Academy of Managed Care Pharmacy (AMCP) is the national professional society of pharmacists promoting the development and advancement of pharmaceutical care in managed health care environments. Current membership exceeds 1,200 members, which represent approximately 190 health care organizations providing comprehensive health care coverage for over 40 million individuals in the United States. AMCP is the only organization whose sole purpose is to represent the interests and views of managed care pharmacy.

The U.S. health care system continues to be in a state of turmoil. Over 35 million citizens lack health care coverage. At the same time health care costs and premiums continue to rapidly escalate. Numerous proposals have been presented to reform the U.S. system in order to address these issues, and the provision of services through managed care is usually one of the primary recommendations.

The individuals and organizations represented by AMCP have been at the forefront in development and provision of pharmaceutical services in managed care settings. Concepts and technologies such as pharmacy benefit design, formularies, provider networks, on line eligibility and claims administration and drug utilization review have been successfully implemented and utilized to provide cost effective pharmaceutical services. Many of these concepts and technologies will serve as prototypes for the reform and further development of other health care services. AMCP recognizes the need for health care reform efforts.

While AMCP does not endorse any

specific reform proposal we feel there are certain elements that are important in any solution. The following outlines those elements.

## **Access to Coverage for All**

AMCP recognizes that health care services are not available on an equitable basis to all of our citizens. The current system has many gaps that result in no coverage, or inadequate coverage, for a large portion of our population. In addition the cost shifting which occurs as a result of care provided for the uninsured or underinsured results in overly inflated charges for payers, business and individuals. AMCP believes that any health care reform solution must include access to a choice of affordable health plan designs for all Americans. In order to accomplish this, barriers to points of entry to the health care system must be removed and health care coverage must be individually portable.

## **Prescription Medication Coverage**

AMCP supports the position that appropriate prescription drug therapies are one most cost effective methods for treating many medical conditions. It is recognized that a well managed pharmaceutical benefit can significantly reduce the cost of surgeries and hospitalizations. Therefore AMCP believes it is essential that coverage of prescription medications is included as a component of any reform proposal. Furthermore we believe that access to prescription medications should be available through any health plan design which

may be implemented.

However, AMCP recognizes the importance of providing the most cost effective prescription benefit. Therefore, we strongly endorse managed care pharmacy concepts such as selective provider contracts, formularies, mandatory generic medications, prior authorization and drug use evaluation and feel it is essential that provisions for concepts such as these are included in reform proposals.

#### **Pharmaceutical Care**

AMCP recognizes that Pharmaceutical Care plays a vital role in the provision of health care services. Pharmaceutical care recognizes the pharmacist as a health care professional with knowledge and resources vital to the success of pharmaceutical therapies. Under this concept the role of the pharmacist is extended beyond the traditional dispensing and distribution functions to focus on optimal patient outcomes.

The pharmacist becomes an active participant on the team of health professionals responsible for clinical management of a patient. By assuming this role, pharmacists have the ability to make significant contributions to the delivery of quality services and care. AMCP strongly believes that proposals for health care reform should recognize the contribution of pharmaceutical care and include this professional activity.

#### **Control of Health Care Costs**

AMCP recognizes that one of the prime factors driving health care reform is the rapidly increasing costs

associated with health care services. Furthermore, AMCP supports the position that in order to accomplish the goals of health care reform, costs must be addressed and contained. Through a variety of the approaches and mechanisms mentioned under the Prescription Medication Coverage section above, managed care pharmacy has successfully demonstrated its ability to manage costs. At the same time it has also demonstrated the ability to ensure a high level of quality. For these reasons, AMCP believes that health care cost solutions will require managed care approaches and health care reform proposals should include provisions and incentives for the use of managed care pharmacy.

#### **Anti-managed Care Initiatives**

On both the state and federal levels, laws and regulations have been implemented which restrict the ability of managed care organizations to administer the pharmacy benefit in a cost-effective manner. Examples of state based initiatives include any willing provider laws, restrictions on the use of formularies and utilization review activities, mandated benefits and mandated providers. On the federal level time consuming waivers are often required to implement managed care programs and "best price" legislation has limited managed care's ability to negotiate contracts with pharmaceutical manufacturers.

AMCP feels that managed care has clearly demonstrated an ability to deliver high quality, cost effective health care which has been responsive to the needs of its members. There-

fore, it is AMCP's position that barriers which do not support the concept of controlling quality and cost should be eliminated in order to allow managed care organizations to function optimally.

#### **Outcomes Based System**

The delivery of medical care is becoming increasingly complex. Technology is providing new, innovative and often dramatic methods of diagnosis and treatment. While the future promises more advances, there is a lack of information concerning the cost effectiveness of many new technologies. AMCP feels it is important to address this issue and that outcomes data should be included in the approval process for new medications. It is essential that unbiased studies are conducted to evaluate and compare alternative diagnostic and therapeutic strategies in order to determine the most cost effective approaches.

In addition, a reliable and systematic mechanism needs to be implemented to convey the results of such investigations to health care professionals responsible for patient care. Information of this nature will serve as a vital tool to aid in diagnostic and therapeutic decisions and will serve to improve the quality of care while managing costs.

#### **Education and Accountability**

In the most efficient health care system, individuals will recognize and assume responsibility for their personal health. They will understand the

*Concluded on page 14...*



# The Pharmaceutical Industry and Health Reform

*Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association*



The Board of Directors of the Pharmaceutical Manufacturers Association believes managed competition will provide the access, cost containment and quality of care required of health care reform while assuring that the industry's ability to discover and develop new and better medicines will not be compromised. PMA believes that the standard benefits package under managed competition should include a prescription drug benefit and that both Medicare and Medicaid beneficiaries should be covered in the managed competition setting. In the interim, PMA endorses incentives for Medicare beneficiaries to join managed-care programs having drug benefits, or if that is not possible, we would support a prescription drug benefit under Part B of Medicare.

Regarding drug coverage under the Medicaid program, most of the reform proposals would integrate Medicaid into managed competition systems and Medicaid patients would receive prescription drug coverage. However, if the Medicaid program were to continue as a separate entity, PMA believes that prescription drug coverage under Medicaid should be extended to at least 100 percent of the poverty level. We support such expanded drug coverage under Medicaid, even though such a policy would significantly increase the rebate obligations of our members to the federal and state Medicaid programs, because we believe the expanded availability of prescription drug therapy will both improve patient care and help reduce the need for more costly Medicaid services.

The pharmaceutical industry recognizes the need for cost containment while managed competition takes

effect. Already, ten major companies representing more than 40 percent of the total market have independently and voluntarily made public commitments to restrain their price increases to the rate of general inflation. The PMA Board continues to urge the Clinton Administration to seek such commitments from other companies.

What follows is material from a position paper distributed by PMA on March 12, 1993.

## Healthcare Reform

The PMA Board believes in:

- A managed competition approach to comprehensive healthcare reform.
- The inclusion of prescription drugs in the standard benefits package under managed competition.
- A prescription drug benefit to Medicare beneficiaries in the managed competition setting but until this becomes possible, PMA endorses developing an approach to provide incentives for Medicare patients to join managed care programs or if that is not possible, to design an outpatient prescription drug benefit under Part B Medicare.
- Medicaid prescription drug coverage to at least 100 percent of the poverty level. Those who can least afford medicines often need them the most.
- Voluntary action to restrain price increases. PMA recognizes the

need for cost containment during the transition from the current system to managed competition. The Association is seeking a method for action, consistent with the antitrust laws, on two fronts:

PMA has been directed by its Board Executive Committee to submit a "Business Review Letter" to the Department of Justice, which, if granted, would permit companies to discuss price restraints and enforcement mechanisms with exemption from prosecution under the antitrust laws.

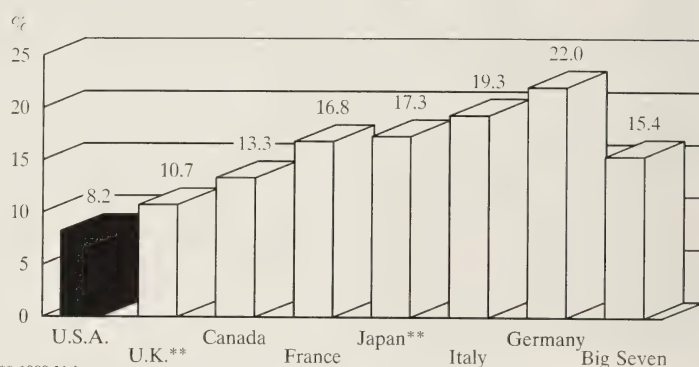
An alternative would be for the administration to seek individual company commitments to restrain price increases. Ten leading manufacturers representing over 40 percent of the total market already have independently and voluntarily made public commitments to restrain their price increases to the Consumer Price Index. The PMA Board has urged the Administration to seek such commitments from other companies.

The PMA Board opposes price controls. The actions above would make price controls unnecessary.

#### Industry's Special Concerns

Healthcare reform must strengthen the national commitment to medical innovation. PMA member companies are spending \$12.6 billion on research and development. Industry research

#### SHARE OF HEALTH CARE EXPENDITURES ON PHARMACEUTICALS - BIG SEVEN COUNTRIES, 1990



\*\* 1989 Values

Source: PMA, 1993, Based on Data from OECD, "U.S. Health Care At the Crossroads," 1992 and U.S. Department of Labor, Bureau of Labor Statistics, 1993.

and development spending in the U.S. amounts to 16.7 percent of U.S. revenues -- highest of all American industries. The industry's research and development investment has been doubling every five years and must be maintained to assure healthcare quality and progress.

Healthcare reform must not undermine the U.S. pharmaceutical industry's competitiveness in world markets. The U.S. industry leads the world in innovation and sales. The industry created 80,000 jobs in the U.S. during 1980 through 1991, while the manufacturing sector as a whole lost more than 1 million jobs. It is one of the few high-tech industries with a positive balance of trade -- \$1.3 billion in 1992. The General Accounting Office recently compared 11 high-technology industries and found that pharmaceuticals maintained a strong international competi-

tive position in the 1980's, while most of the ten other industries experienced some decline.

Healthcare reform must take into account the role of pharmaceuticals in holding down healthcare costs. Prescription drugs help shorten hospital stays, avoid surgeries and postpone nursing home confinements. Restrictions on access to drugs can be counterproductive (See Soumerai, et.al., *New England Journal of Medicine*, October 10, 1991).

#### Pharmaceutical Prices

Price increases have slowed. According to the Bureau of Labor Statistics (BLS), manufacturers' price increases for prescription drugs for the 12-month period ending in January were the smallest in 15 years. They have declined steadily since 1989, dropping from 9.5 percent in

that year to 5.1 percent during the 12 months ending in January -- a 46 percent decrease. Because of economic analyses showing that the BLS index actually overstates price increases, BLS is changing its methods for measuring pharmaceutical price increases.

Companies are voluntarily holding down prices. Ten companies representing more than 40 percent of U.S. sales have pledged to keep prices at or below inflation -- and all are honoring their pledges.

Pharmaceuticals are not a key factor in the rapid rise in total health-care expenditures. Outpatient prescription drugs as a percent of national health-care expenditures have declined in the U.S., dropping from 8.9 percent in 1965 to 4.8 percent in 1991. While health-care costs have increased rapidly, rising from 5.9

percent of Gross Domestic Product (GDP) in 1965 to 13.2 percent in 1991, the share of GDP spent on prescription drugs has remained relatively constant for three decades -- at 0.53 percent of GDP in 1965 and 0.64 percent in 1991.

New drugs are entering the market at prices lower than the prices of existing market leaders. Of new chemical entities which were approved by the FDA for marketing in the U.S. during 1991 and 1992, 24 of these were launched into therapeutic areas where competing pharmaceuticals existed. In these cases, 21 of the 24 entered the U.S. market at a price lower than the price of the existing market leader. In many cases, these prices were substantially lower, averaging 18 percent lower for pharmaceuticals treating chronic ailments, and seven percent lower for

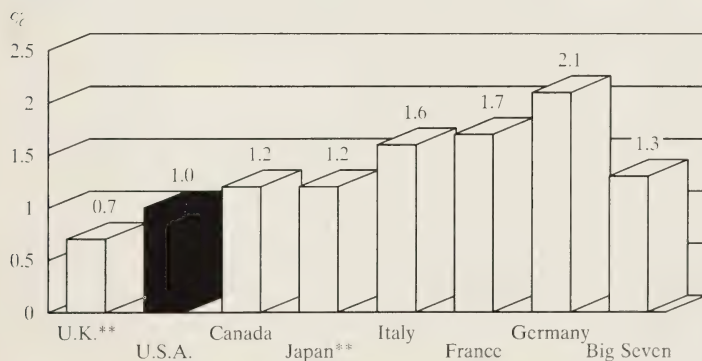
pharmaceuticals treating acute ailments.

### International Prices

The General Accounting Office report of September 30, 1992 makes inaccurate comparisons of the prices of prescription drugs in Canada and the U.S.:

- Using the same data used in the GAO study, Dr. Stephen Schondelmeyer, professor of pharmaceutical economics at the University of Minnesota, weighted the price comparisons using Canadian sales data -- a necessary step for fair comparison -- and found Canadian prices to be only 12.2 percent lower than U.S. prices. He also found that new products introduced to the Canadian market since 1987 were actually 12 percent *higher* in Canada than in the U.S..
- The GAO study failed to take into account the availability of generics in the U.S.. Of the 121 drugs compared in the study, generic versions of one-third of them are available in this country. A key method by which the U.S. government has chosen to influence the pharmaceutical market is to expedite the approval of generic versions of brandname drugs as soon as their patents expire, under the 1987 Waxman-Hatch Act. The GAO did not consider these lower generic prices in their comparisons.

### SHARE OF GDP SPENT ON PHARMACEUTICALS BIG SEVEN COUNTRIES, 1990



\*\* 1989 Values

Source: PMA, 1993. Based on Data from OECD, "U.S. Health Care At the Crossroads," 1992.



Many of the industry's newest products have been launched with U.S. prices similar to or lower than the prices in other industrialized countries. While individual product prices continue to vary, an analysis of the top-selling 100 pharmaceuticals in 1990 revealed that products launched in the U.S. during the prior five years had a negligible price premium (0.2 percent) to the average prices across six major European countries.

U.S. per capita expenditures on pharmaceuticals are about average for an industrialized country. U.S. expenditures are approximately four percent lower than the Big Seven average if all currencies are converted into U.S. dollars using purchasing power parity. [Table One]

Pharmaceuticals accounted for 8.2 percent of total health care expenditures in the U.S. in 1990, considerably lower than the Big Seven average of 15.4 percent. Japan, Italy, Germany and France all present shares between 16.8 percent and 22.0 percent. [Table Two]

Pharmaceuticals rank slightly below the average of major industrial countries when pharmaceuticals' share of Gross Domestic Product is compared. The share that drugs consume of U.S. GDP is 1.0 percent, compared to the Big Seven average of 1.3 percent. Only the United Kingdom has a lower GDP share attributed to pharmaceuticals -- 0.7 percent.

The average U.S. worker pays less for his annual pharmaceutical supply than workers in most industrialized nations. Comparing countries' drug expenditures on the basis of average wage rates of comparable workers is another way of standardizing expendi-

tures. The U.S. production worker in manufacturing has to work only about 14.4 hours to pay for his average annual supply of pharmaceuticals, compared to 16.0 hours for Canadians, 22.5 hours for Germans and 22.1 hours for Japanese.

### **A Different Market in the 1990's**

Though many studies of the industry focus on market conditions and responses of the 1980's, the pharmaceutical industry is facing far different conditions today.

Rapid expansion of research and development capability in the industry means that even breakthrough drugs now commonly face strong competition from innovative products long before patent expiration.

More than 80 major branded pharmaceutical products will face generic competition by 1995. These products currently have nearly one-third of industry sales -- an estimated \$20 billion share by 1995.

Under the Omnibus Budget Reconciliation Act of 1990, industry Medicaid rebates to state and federal bureaus will total over \$6.4 billion in the first five years -- \$1.2 billion last year alone -- doubling the estimates made by Congress when the law was enacted. This is profoundly impacting the profitability of companies.

The growth of managed care programs has increased pharmaceutical price competition. That trend will accelerate sharply under managed competition. **R**

## Mail-Order Pharmacy Sues Pharmacist

David B. Brushwood, J.D.



The defendant in a recent lawsuit brought in Mississippi was an Alabama mail-order pharmacy that allegedly delivered incorrect medications by mail to a patient in Mississippi. The patient alleged that as the result of his ingestion of these medications, he suffered physical and mental injuries, and became violent and abusive toward his wife and children.

The pharmacy filed an action for indemnity against the pharmacist who had actually filled the patient's prescriptions. In effect, the pharmacy sought to bring the pharmacist into the Mississippi lawsuit, and have the court hold the pharmacist personally liable to reimburse the pharmacy for any judgment against it based on this incident.

The court noted that a non-resident party can be brought into litigation only if the party has purposefully established "minimum contacts" with the state in which a lawsuit has been filed, and if the lawsuit does not offend traditional notions of fair play and substantial justice.

Of course, by doing business in Mississippi, the pharmacy had established minimum contacts with that state. But there was no evidence that the pharmacist had any contact with Mississippi. A court does not have jurisdiction over an employee simply because it has jurisdiction over the employer. The pharmacy could produce no evidence showing that the pharmacist even knew, when he filled the prescriptions, that the patient who brought this lawsuit lived in Mississippi.

Moreover, the court held that it would be unfair to have a dispute between two Alabama parties (the pharmacy and pharmacist) resolved by a Mississippi court. Although the patient and his family suffered their injuries in Mississippi, the action upon which the indemnity claim was based (the alleged mistake in prescription filling) occurred in Alabama. Therefore, any right of the pharmacy to indemnification from the pharmacist will have to be resolved in Alabama, if the Mississippi court holds against the pharmacy in the case brought by the patient against the pharmacy.

The pharmacy was not permitted to sue its own pharmacist as part of the Mississippi case, but the possibility of that lawsuit occurring in Alabama after the resolution of the Mississippi lawsuit continues to exist. R

Based On: *Bumgarner v. Carlisle Medical, Inc.*, 1993 Westlaw 4452 (S.D.Miss. 1993)

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# Continuing Education

## Continuing Education Quiz

April 1993 -- Health Care Reform

This month's questions are taken from the articles on national health care reform that appear in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by October 31, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

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1. One of the most cost effective methods of treating disease and medical conditions is:
  - a. surgery
  - b. pharmaceutical products
  - c. hospitalization
  - d. long term care
2. A common theme appearing in the health care reform positions of APhA, NARD, NACDS, PMA, and AMCP is:
  - a. price controls
  - b. pharmacy/patient freedom of choice
  - c. pharmacy products/services benefit
  - d. discriminatory pricing
3. Which two organizations addressed compensation for pharmacy services in their reform proposals?
  - a. APhA and NARD
  - b. NARD and PMA
  - c. APhA and AMCP
  - d. PMA and AMCP
4. Which two organizations believe access to patient information is needed to provide effective pharmaceutical care?
  - a. AMCP and NARD
  - b. NARD and PMA
  - c. APhA and AMCP
  - d. NARD and APhA
5. According to one position paper, a competitive pharmacy marketplace includes all of the following except:
  - a. drug prices based on bidding/market share
  - b. pharmacy freedom of choice
  - c. unlimited provider networks for any third-party program
6. Which pharmacist organization most strongly promotes pharmacy/patient "freedom of choice?"
  - a. APhA
  - b. ASHP
  - c. NARD
  - d. NACDS
7. How does the PMA propose to contain drug costs?
  - a. price controls
  - b. discriminatory pricing
  - c. restraints on price increases to the CPI
  - d. OBRA '90 rebates extended to all purchasers
8. Prices of new products marketed in Canada are \_\_\_\_\_ in the U.S..
  - a. higher than
  - b. lower than
  - c. the same as
9. Which organization opposes drug price controls?
  - a. NARD
  - b. APhA
  - c. NACDS
  - d. PMA
10. The managed care setting provides cost-effective pharmaceutical services by all of the following *except*:
  - a. consumer access to the pharmacy of choice
  - b. drug utilization review
  - c. mandatory generic substitution
  - d. formularies



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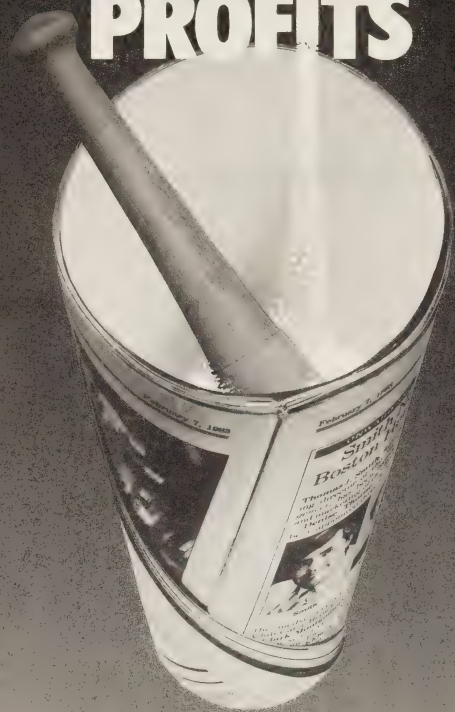
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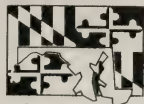


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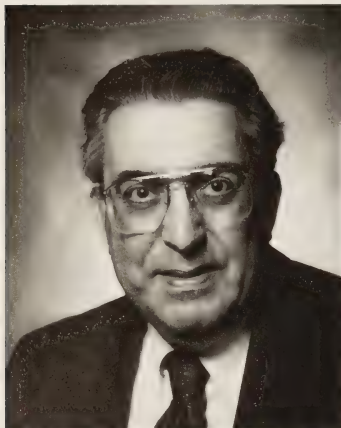
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## President's Commentary

Nicholas C. Lykos, P.D., President



One of the most amazing things about the American democratic system is the smooth transfer of power between political parties. Before, during and after the recent presidential elections, journalists were busily comparing our election process to nightmare countries in Europe and Central America where 10, 20 or more political groups fight amongst each other for government control. Would-be presidents are assassinated, coups are a common occurrence, and citizens are powerless captives of a process that we Americans take for granted.

This past legislative session, I watched while pharmacists were pitted against other pharmacists in a fight over the University of Maryland School of Pharmacy's all-Pharm.D. program. Opponents, not satisfied with having killed the program at the Association, School, University, or Board of Regents levels went to the Maryland General Assembly to plead their case.

Regardless of how individuals personally feel about the all-Pharm.D. program, I think it's important for all MPhA members to understand the long process the University of Maryland School of Pharmacy used to come to this decision. This was not a change made lightly by the School or its faculty. It was certainly not a change supported by 100% of MPhA members, nor 100% of MSHP's members, nor even 100% of pharmacists in the state. However, the leadership of our Association -- both the Board of Trustees and the House of Delegates -- made the professionally correct by politically difficult decision to support the School's efforts.

Now, while I understand that everyone has a right to petition his or her government to correct a perceived wrong, I have to question the wisdom of pharmacists using the legislature to solve disagreements over the profession's future -- especially when pharmacy already suffers from too much legislation, too much regulation, and too much interference from non-pharmacists. I have to question the intentions of those focusing on today's economics and today's profession instead of looking ahead to the demands and needs of a profession five or ten years away.

Perhaps pharmacists need to take a lesson from the average American. Perhaps we need to start presenting a united front to our legislators. Whenever we appear divided on one issue, legislators and regulators assume that we can be divided on other issues. The sad thing is, we sometimes can.....

R



# The Report from Annapolis

Robin F. Shaivitz, MPhA Legislative Consultant



The 1993 Legislative Session can be described in one word -- intense. While the session's original forecast was for a mild and relatively uneventful ninety days, this prediction turned out to be completely false -- especially for health care providers. Appearing below is a summary of the most important of the more than 58 bills MPhA tracked on behalf of pharmacists.

## **SB 8 and HB 656**

Senator Habern Freeman pre-filed Senate Bill 8. This bill increased the crime for forging a prescription from a misdemeanor to a felony. The bill was comprehensive in that it defined forging as any attempt "to possess, pass, utter, make, or manufacture a false, forged, or altered prescription for a controlled dangerous substance or controlled paraphernalia." The penalty for prescription forgery included a fine of up to \$25,000, imprisonment up to 10 years, or both. A similar bill, House Bill 656, was sponsored by Delegate Brewster. This bill provided three separate penalties for forgery of a prescription. The first offense carried a fine up to \$5,000 and/or two years in jail, the second carried a fine of up to \$10,000 and/or five years in jail. The third offense carried the same penalty as did the Senate bill, \$25,000 and/or 10 years in jail. The House Bill was defeated by the Judiciary Committee while the Senate version passed. The Senate bill then also died in the House Judiciary committee. As indicated last year, the House Judiciary Committee opposes increasing the nature of the crime to a felony.

## **SB 513 and HB 1369**

Senator Paula Hollinger sponsored legislation to permit nurse practitioners to dispense starter doses of drugs in medical facilities under certain circumstances. MPhA supported the bill with restricting amendments that required the nurse practitioners to follow the same labeling, record keeping, and inspection requirements of pharmacists. The Economic and Environmental Affairs committee passed the bill and adopted our amendments. The bill passed both the House and Senate. MPhA will track this issue closely as regulations are developed by the Board of Nursing.

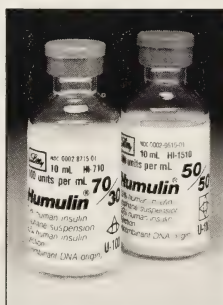
House Bill 1369 was a bill to provide for prescribing privileges by physician assistants in clinically approved inpatient settings that was filed on behalf of the Board of Physicians Quality Assurance and the Department of Health and Mental Hygiene. We opposed this bill because the language of the bill was too open ended. In addition, MPhA did not wish to see a repeat of the problems pharmacists had with nurse practitioners. Because of our opposition, the bill was passed by the House with several clarifying and limiting amendments offered by Delegate Rosemary Hatem Bonsack, a physician, who concurred with our opinions. The Senate Environmental Affairs Committee amended the bill to allow the prescribing of drugs in outpatient situations as well as inpatient settings. With these two




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versions being in conflict, neither side was willing to reconsider. A Conference committee was appointed to resolve the differences and ultimately, with Chairman Guns on our side on this issue, the bill died in the Conference committee.

### **Senate Bill 154**

This bill was intended to repeal a provision which called for the termination of the coverage and copayment requirements for the Maryland Pharmacy Assistance Program. The bill was amended in the Senate Finance Committee to extend the program until June 30, 1995 instead of a permanent extension. The bill, with this amendment, smoothly passed by the Senate and House.

### **SB 238 and HB 687**

The Freedom of Choice bill was cross-filed in both houses under the sponsorship of Senators Young, and Baker, and Delegate Teitelbaum. This bill would allow any willing pharmacy to review and accept any HMO contract. Our lobbying efforts at the beginning of session were so successful that our support amongst the committee members was overwhelming. We also began this summer lining up support from other organizations including The United Seniors of Maryland, The Baltimore Jewish Council, and the Retail Merchants Association. Senator Baker and Young's bill was given a favorable report by the Senate Finance Committee. The bill was amended on the Senate floor to exempt HMO's which already have their own in-house, on site pharmacies. The bill passed to the House on

a vote of 40-0 on third reading. The bill was then sent to the House Environmental Matters Committee where Chairman Ron Guns held the bills hostage. Despite fierce lobbying on our part, Chairman Guns refused to allow the bills to be voted on by his committee saying he was afraid that with the passage of this bill, all other health care providers would follow suit and want to be let into the HMO networks, thereby defeating the purpose and cost effectiveness of managed care. We worked with House Speaker Mitchell, Senate President Miller, and all other influential parties to convince Chairman Guns that he was doing the wrong thing by not allowing either of these bills out of his committee. Finally, the day before the final day of session, Delegate Guns allowed the Senate bill out of his drawer in an emasculated form. We talked long and hard with the committee members to accept this version which we crafted with Delegate Guns' authorization. His committee passed the amended bill as did the entire House. The new version of Senate Bill 238 then had to return to the Senate for approval on the amendments. Senate Finance Committee Chairman O'Reilly balked at once again having to consider a bill that he was personally opposed to but had allowed out of his Committee.

Basically, the amended version accomplishes two things. It prohibits an HMO from charging a network application fee to any pharmacy. It also requires the HMOs, within 10 days, to notify the Maryland Pharmacists Association of new contract offers or changes to existing contracts so that MPhA can alert all interested licensed pharmacists.

Only after many long hours of lobbying on the last day, Senator O'Reilly acquiesced. The Senate vote

was 42 to 1. Senators Baker and Young helped pressure chairman O'Reilly into bringing the amended bill onto the Senate floor for final passage.

### **House Bill 371**

Relating to the liquidation of HMO's, a bill was sponsored by pharmacist Delegate Donald Elliott to give health care providers immediate priority in claims received after claims of the members when an HMO is being liquidated either because it is going out of business or it is being bought up by another health entity. MPhA strongly supported the measure. House Bill 371 was heard in the Economic Matters committee who gave it a favorable report. It sped through the House on third reading with a vote of 135-0. The bill was killed in the Senate Finance Committee.

### **HB 827 and SB 692**

These companion bills were drafted so that the University of Maryland School of Pharmacy would not be able to offer the proposed all-Pharm.D. program. Amidst heavy lobbying by MPhA, MSHP, individual pharmacists, the University, School and the Board of Regents, the Senate Economic and Environmental Affairs Committee heard the bill and promptly voted against it. In the meantime, the House Appropriations Committee heard the HB 827 version and sat on it.

*Continued on Page 18....*



## 1993 Legislation Affecting Pharmacy

### *Bills Introduced in the Maryland House*

Bill	Title	Sponsor	Description	MPhA Position	Status
House Bill 98	CDS -- Penalties	Arnick	Increases fine penalties for forged prescriptions and also adds paraphernalia to nonprivileged medical communication	Monitor Only	Killed
House Bill 102	CDS Penalties -- Diversion in Lieu of Prosecution	Montague	Would allow State's Attorney to seek rehab instead of jail/fine for first time Rx forgers.	Support and Amend	Killed
House Bill 150	Insurance - Health Purchasing Commission Act	Economic Matters	Provides for a new regulatory program governing certain health benefit plans.	Monitor Only	Killed
House Bill 158	Nonprofit Health Service Plans	Taylor	Requires stricter guidelines for the management of non-profit health service plans. (anti-Blue Cross)	Monitor Only	Killed
House Bill 159	Nonprofit Health Services Plans - Trustees and Directors	Taylor	Provides standards for the qualification, election, and tenure of non-profit health insurance directors and trustees. (anti-Blue Cross)	Monitor Only	Killed
House Bill 193	Health Insurance -- Coverage for Grandchildren	Curran	Provides for continuation or establishment of health insurance coverage for certain dependent grandchildren	Monitor Only	Enacted
House Bill 207	Small Employer Group Health Insurance	Economic Matters Committee	Creates regulation of small employer group health insurance plans with restrictions on rates, coverage, etc.	Monitor Only	Killed
House Bill 238	Nonprofit Health Service Plans - Regulation, Solvency and Operations	Licensing & Regulation	Strengthens regulation of non-profit health insurers especially in areas of solvency and cash assets	Monitor Only	Enacted
House Bill 271	Shoplifting and Employee Theft - Immunity from Criminal Prosecution	Rynd	Prohibits criminal prosecution of shoplifters if damage is less than \$350 and shoplifter pays the damage plus \$100 in penalties	Monitor Only	Withdrawn

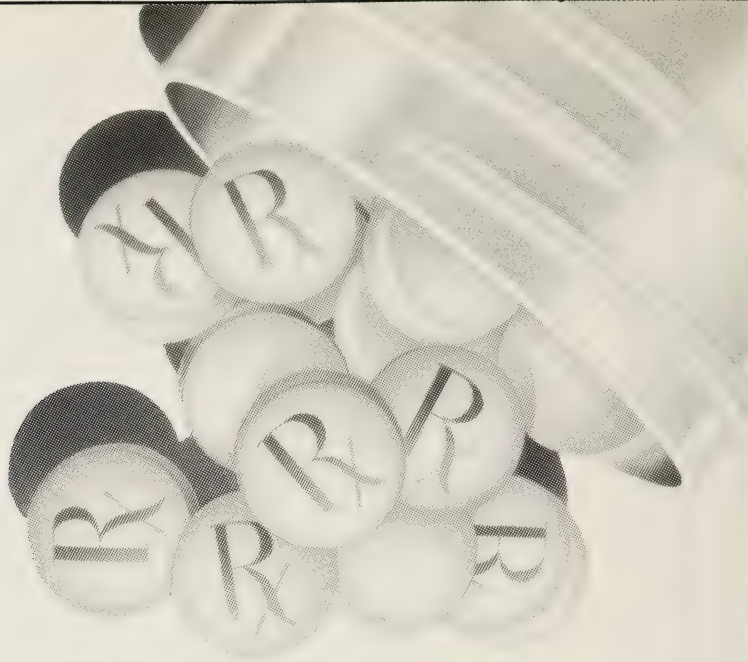
Bill	Title	Sponsor	Description	MPhA Position	Status
House Bill 554	Discriminatory Pricing	Elliott, Huff, et.a.	Requires pharmaceutical manufacturers to sell to all pharmacies/purchasers at the same price. Does not count volume discounts.	Support	Refer to Summer Study
House Bill 564	Health Insurance Preexisting Conditions	Thomas, et. al.	Prohibits certain insurers from exempting preexisting conditions for more than 10 months from date coverage begins	Monitor Only	Killed
House Bill 582	CDS - Correctional Facilities	Huff, Cadden, Kolodziejski	Increase penalties for delivering a CDS illegally to a prisoner or inmate	Monitor Only	Killed
House Bill 605	Health Insurance - Payments for Rental of Medical Equipment	Taylor	Requires insurer to pay monthly rental rate of medical equipment, prevents termination of coverage without notification to patient and provider	Support	Enacted
House Bill 606	CDS - Forfeiture Proceedings	Harkins	Clarifies seizure and forfeiture of personal property for violations	Monitor Only	Killed
House Bill 656	CDS - Prescriptions, Forgery	Brewster	Makes forging or attempt to pass a forged Rx a felony offense	Support	Killed
House Bill 659	CDS - Minimum Fines	Rosapepe	Requires minimum fines for certain CDS violations	Monitor Only	Killed
House Bill 687	HMOs - Pharmaceutical Services	Teitelbaum, Weir, LaMotte, Bonsack, Bozman, Elliott, Hubbard, Kelley, Murphy, Owings, Perry, Redmer, Sulin, Heller, Roesser	Freedom of Choice bill, House version	Support	Killed
House Bill 738	HMO's - Providers - Payment of Claims	Donoghue	Requires HMOs to reimburse providers at either the billed rate or their usual and customary charge	Support	Killed
House Bill 783	Workers Compensation Cases - Generic Drugs Required	Hurson	Requires generic drugs to be dispensed by pharmacists for workers compensation cases. Not endorsed by Chamber of Commerce.	Oppose	Killed
House Bill 793	CDS - Minors - Penalties	Ports, Redmer	Requires a minimum sentence for anyone using a minor in the commission of a CDS offense	Monitor Only	Killed

<b>Bill</b>	<b>Title</b>	<b>Sponsor</b>	<b>Description</b>	<b>MPhA Position</b>	<b>Status</b>
House Bill 799	CDS - Loss of State Payments	Ports, Redmer, Fulton	Halts any assistance, subsidy, entitlement, or other State monies if recipient is convicted of CDS violations	Monitor Only	Killed
House Bill 827	University of Maryland -- Pharm.D. Program	Elliott, Bozman, Gary, Dixon, Dewberry	Requires UMAB School of Pharmacy to retain the B.S. pharmacy program.	Oppose	Killed
House Bill 863	CDS - Sentencing	Harkins, Franks	Requires minimum sentences for individuals convicted of certain CDS violations and conspiracy	Monitor Only	Killed
House Bill 895	HMOs - Redomestication	Frosch, Hurson, Barve	Permits out-of-state HMOs to become a domestic HMO with all rights, privileges, etc.	Monitor Only	Enacted
House Bill 1356	HMOs - Noncontract Providers	Weisengoff	Requires HMO's to pay for services at U/C or other rate if provider gives service and is not under contract with the HMO	Support	Killed
House Bill 1359	Health Insurance Reform		A massive overhaul of the Maryland health care system, the bill establishes a cost-containment Commission. Pharmacy is included in some sections however the final impact on the profession has yet to be determined.	Monitor Only	Enacted
House Bill 1369	Physician Assistant Prescribing	Chairman (DHMH)	Provides for prescribing privileges by PA's in clinically approved inpatient settings	Oppose	Killed

For a copy of any of these bills, please call the MPhA offices at (800) 833-7587 or FAX us a request at (410) 727-2253.



<b>Bill</b>	<b>Title</b>	<b>Sponsor</b>	<b>Description</b>	<b>MPhA Position</b>	<b>Status</b>
House Bill 285	Medical Assistance - Late Payment to Providers	Taylor	Requires Medical Assistance to pay interest if good claims are not paid in 30 days	Monitor Only	Killed
House Bill 286	Health Insurance - Managed Competition	Economic Matters	Creates a new regulatory program using regional advisory boards to establish rates and health benefits	Monitor Only	Killed
House Bill 368	CDS - Fraud	Governor's Drug & Alcohol Abuse Commission	Establishes penalties for falsifying or using false documents in connection with certain CDS offenses to up to \$10,000 and/or 5 years in prison	Monitor Only	Killed
House Bill 371	HMO's - Bankruptcy Settlement	Elliott	Makes providers the second group, after patients, to be paid in case of an HMO bankruptcy.	Support	Killed
House Bill 386	Health Occupations - Licenses and Notices	Menes	Requires health boards (including pharmacy) to provide tax department with a list of licensees, addresses, and social security numbers	Monitor Only	Killed
House Bill 389	Task Force to Study Health Professional - Client Sexual Exploitation	Teitelbaum, et. al.	Establishes a task force to study the sexual exploitation of the public by health professionals	Monitor Only	Enacted
House Bill 394	HMO's Emergency Services - Payments	Curran	Allows providers to charge an HMO patient for emergency services if the HMO denies payment	Monitor Only	Killed
House Bill 409	Maryland Universal Health Care	Pinsky, et. al.	Establishes a universal health care plan for Marylanders	Monitor Only	Killed
House Bill 449	Health Insurance -- Unified Health Care System	Hurson	Establishes a unified health care plan for Marylanders including definition of minimum benefits	Monitor Only	Killed
House Bill 460	Health Insurance -- Small Employer Group Reform	Administration	Changes governing of small employer group programs for rating and underwriting	Monitor Only	Killed
House Bill 491	CDS -- "White Collar" Crime	Kelley, et. al.	Providing for punishment of CPAs, bankers, etc. who are involved in handling more than \$500 of ill-gotten gains from CDS violations	Monitor Only	Killed
House Bill 553	CDS -- Conspiracy, Sentencing	Kelly, Donoghue	Adds conspiracy to violate a CDS law a felony	Monitor Only	Killed



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<b>Bill</b>	<b>Title</b>	<b>Sponsor</b>	<b>Description</b>	<b>MPhA Position</b>	<b>Status</b>
Senate Bill 513	Nurse Practitioners - Authority to Dispense Prescriptions	Hollinger	Permits nurse practitioners to dispense starter doses and drugs in certain medical facilities under certain circumstances	Support and amend	Enacted and Amended
Senate Bill 514	Home Medical Equipment Providers	Hollinger, Collins	Requires registration of DME providers with DHMH and comply with state/federal regulations.	Oppose	Killed
Senate Bill 537	HMO's Redomestication	Ruben, Sher, Denis	Permits out-of-state HMOs to become a domestic HMO with all rights, privileges, etc.	Monitor Only	Enacted
Senate Bill 554	CDS - Conspiracy Sentencing	Jimeno	Adds conspiracy to violate a CDS law a felony. Same as HB 553.	Monitor Only	Killed
Senate Bill 556	Maryland Health Insurance Purchasing Cooperative	Hollinger, et. al.	Creates regional purchasing groups for health insurance ratings	Monitor Only	Killed
Senate Bill 692	UMAB School of Pharmacy - Pharm.D. Program	Dorman, et. al.	Requires UMAB School of Pharmacy to maintain a B.S. degree program.	Oppose	Killed
Senate Bill 770	HMOs - Agreements with Out-of-State Providers	Ruben, Levitan	Prohibits HMOs from using out-of-state providers exclusively if a provider is in state within 20 miles of a subscriber.	Support	Killed
Senate Bill 829	Health Insurance - Billing for Services	Derr	Requires a health care service bill to be in simplified language.	Monitor Only	Killed
Senate Bill 844	CDS - Minimum Fines AIDS Infected Children	Hughes	Establishes a special fund to help AIDS infected children from fines paid from CDS offenses.	Monitor Only	With drawn

For a copy of any of these bills, please call the MPhA offices at (800) 833-7587 or FAX us a request at (410) 727-2253.





# Catch the Winning Spirit!

## Sunday, June 13, 1993

1:00 - 5:00 pm Registration

2:00 - 4:00 pm Welcoming Reception  
*Sponsored by Qualex*

4:00 - 6:00 pm **Health Care Reform in Maryland --  
What the Future Holds**

Maryland recently made headlines when it became the first state to pass major health reform legislation. However, even those closest to the bill recognize that there is much yet to be worked out. MPhA has invited three Maryland legislators and its lobbyist to give their perspectives on what the new legislation means to consumers and to pharmacists.

9:00 - 11:00 pm Desserts Galore Reception  
*Sponsored by Alco Health Services*

## Monday, June 14, 1993

8:00 - 9:00 am Continental Breakfast  
*Sponsored by Upjohn*

9:00 - 12:30 am **Pharmaceutical Care -- The Role of  
the Pharmacist in Patient Outcomes**

Pharmaceutical Care is fast becoming a popular phrase in the pharmacy literature. What does it mean and why should pharmacists pay attention to it? Two eminent speakers at Montefiore Medical Center will help you understand the pharmaceutical care process and how, with some modifications to what you are already doing, develop a systematic and comprehensive plan to provide pharmaceutical care in your practice.

*Sponsored by The Upjohn Company*

10:00 - 12:00 am SAMPA Brunch and Fashion Show

12:30 - 2:30 pm Trade Exposition and Luncheon  
*Lunch Sponsored by Marion Merrell Dow*

2:30 - 4:30 pm MPhA House of Delegates  
First Business Session

The first session of MPhA's democratic governing body will be devoted to reports from MPhA's President, Treasurer and Executive Director.

6:30 - 10:00 pm Annual Crab and Chicken Feast at  
Berlin Fire Hall

## Tuesday, June 15, 1993

8:00 - 9:00 am Bagel Breakfast  
*Sponsored by the Sheraton Hotel*

9:00 - 11:00 am **Pharmaceutical Care -- Assessing  
Nutritional Needs in Ambulatory  
Patients**

Gail Rosen, Pharm.D., Director of Nutrition Support Services at the University of Maryland Medical System will show community pharmacists how to screen patients for nutritional risk. Since so many medications are used by the elderly, who oftentimes are at the highest risk for nutritional problems, pharmacists should be able to identify potential drug-nutrient interactions and minimize drug induced risk factors.

*Sponsored by Ross Laboratories*

10:00 - 11:30 am SAMPA Brunch and  
Business Session

11:30 - 12:30 am **Pharmaceutical Care and Maryland  
Pharmacy**

In October 1992, representatives of Maryland's pharmacy organizations met at a two day Consensus Conference to discuss the future role of pharmacy. The results of that Conference was a new spirit of cooperation between the organizations and a set of clear issues, goals and objectives to be mutually accomplished. This interactive program will seek practicing pharmacists' opinions on the which issues should be tackled first.

*Sponsored by Hoechst-Roussel*

## Registration Information

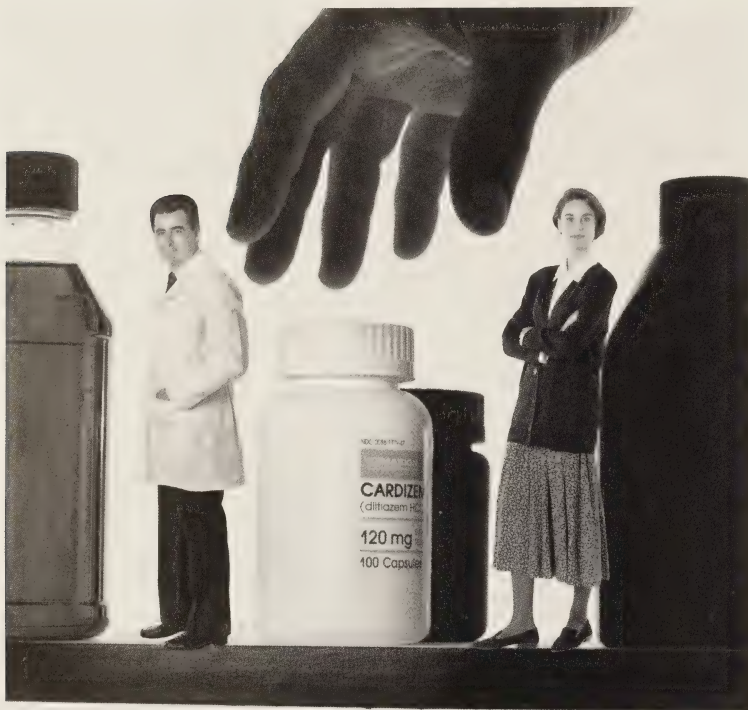
Need additional information on registering for MPhA's 111th Annual Convention? Simply give us a call at (800) 833-7587 and we'll make sure you're part of the winning spirit!

## 1993 Legislation Affecting Pharmacy

### *Bills Introduced in the Maryland Senate*

Bill	Title	Sponsor	Description	MPhA Position	Status
Senate Bill 8	Controlled Dangerous Substances -- Forgery	Freeman	Makes attempts to pass or forge a CDS prescription a felony. This is a repeat of 1992 legislation.	Support	Killed
Senate Bill 104	State Board of Pharmacy	Administration	Repeals a requirement that a certain percentage of Board of Pharmacy members vote in favor of a disciplinary action	Monitor Only	Enacted
Senate Bill 132	CDS - Fentanyl - Penalties	Haines	Adds fentanyl to the list of drugs that are brought into the state illegally.	Monitor Only	Enacted
Senate Bill 154	Maryland Pharmacy Assistance Program	Department	Repeals the sunset provision of the MPAP and makes it permanent. Amended to extend program until 1995.	Support	Enacted and Amended
Senate Bill 157	Home Health Agency - Defined	Department	Clarified definition of home health care agency as one that provides nursing services, health aid services and at least one other HHC service.	Monitor Only	Enacted
Senate Bill 158	Exempting a Domiciliary Care Home from Certain Requirements	Department	Exempts domiciliary care homes from state regulation if regulated by a county	Monitor Only	Killed
Senate Bill 168	Civil Penalties -- Violations on Elderly Housing	Office on Aging	Allows Office on Aging to impose monetary penalties for violations of certain regulations relating to the care of the elderly in sheltered housing	Monitor Only	Enacted
Senate Bill 238	HMOs - Pharmaceutical Services	Baker, Young	Requires an HMO to allow any willing pharmacy provider to review and accept a participation contract.	Support	Enacted and Amended
Senate Bill 349	Health Insurance Small Employer Group Health Insurance Reform	Miller Administration	Changes governing of small employer group programs for rating and underwriting	Monitor Only	Killed
Senate Bill 502	HMOs - Providers - Payment of Claims	Della	Requires HMOs to reimburse providers at either the billed rate or their usual and customary charge	Monitor Only	Killed

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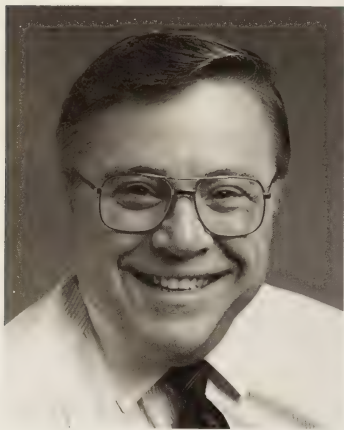
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# Positioning Theory and Market "Creneaus"

Bruce R. Siecker, Ph.D., R.Ph., Executive Vice President, NWDA



Twelve years have passed since the publication of a still little known classic in marketing theory and practice. Even today few pharmacists would ever think to pick up a copy of *Positioning: The Battle for Your Mind* by Al Ries and Jack Trout. More should!

This deceptively concise roadmap of how the human mind hears and interprets promotional messages is an excellent tool for those responsible for managing a pharmacy and directing their own professional lives. It's useful for anyone involved in everyday affairs of commerce, whether it's selling a product, a service or one's self.

The authors -- two street smart veterans of Madison Avenue -- show how most people misinterpret the role of communication in business and demonstrate how very, very little communication actually takes place today. Apparently, we are bombarded with so many messages -- from too many companies, too many products and too many services -- that the mind is overwhelmed to the point that most messages become background noise that produces no recognition or reaction. In essence, the mind fails to notice most messages and discards much of what reaches it.

Ries and Trout believe that most people, in order to deal with our over-communicated society, have learned to peg products and services on a mental ladder. In order to succeed today, an advertiser (product, service or person) "... must create in a prospect's mind (consumer, employer, banker, etc.) a position that takes into consideration not only a company's (or, product, service or person) own strengths and weaknesses, but also of

its competitors as well."

## Enter the Positioning Era

In the Positioning Era, which is how Ries and Trout label the present, it is not enough simply to invent or produce something new or even to have a clearly better product or service. It may not even be necessary to have the *best* product or to be physically in the market *first*. The "must" is to get into the prospect's mind first and for the prospect to "position" the product in a favorable way. If you cannot get and hold a position in the mind of the prospect, market success will be difficult to achieve today.

A comparison between the human mind and a computer helps demonstrate these concepts. A computer by definition accepts all information fed into it. If proper letters and symbols are used and the operator pushes the right keys in the right way, a computer accepts all information. A computer treats information in the same manner, making no decision on whether to store or not store, remember or not remember data.

Not so with the human mind! The human mind, in fact, does just the opposite. It readily accepts information that is consistent with its current thinking or prior knowledge and experience -- we see and hear what we expect to see and hear -- and actively rejects that which "does not compute." The average person likes hearing what is agreeable and what matches experience, but has a great deal of trouble accepting that which conflicts with past experience or current thinking. Paradigm thinking, which is popular in today's business

# The 111th Annual MPhA Convention

12:30 - 2:30 pm Trade Exposition and Buffet Luncheon

2:30 - 4:30 pm **Powerful Patient Counseling Skills**  
Nationally renowned speaker Richard Drinon of Executive Edge will help pharmacists refine their patient counseling skills through a recognition of how first impressions can lead to fixed projections. If you find yourself frustrated with difficult patients, this is a seminar you must attend! *Sponsored by Searle*

9:00 - 11:00 pm Catch the Winning Spirit  
President's Reception

Come enjoy the sights and sounds of an evening of horse racing without leaving the hotel! Betting-for-fun and plenty of light food are a guaranteed winner.

## Wednesday, June 16, 1993

7:30 - 8:30 am Bagel Breakfast  
*Sponsored by the Sheraton Hotel*

8:30 - 10:00 am **Pharmaceutical Care -- Reaching the Needs of Special Patient Populations through Diabetes Education**

Presented by Cheryl Hunt, R.N., C.D.E., president of the American Association of Diabetes Educators, this 1.5 credit program will aid pharmacists in assessing special patient populations and evaluating community resources to improve patient outcomes.

*Sponsored by Eli Lilly & Company*

10:00 - 12:00 noon MPhA House of Delegates  
House Speaker Ernie Testerman and Vice Speaker Alisa Billington will preside over the Second General Business Session. The agenda will include a discussion of member submitted resolutions, election of House officers and the installation of the MPhA's newest trustees.

12:30 - 1:30 pm MPhA Student Careers Luncheon  
*Sponsored by Giant Pharmacies*

6:00 - 7:00 pm MPhA Banquet Reception  
*Sponsored by McKesson*

7:00 - 9:30 pm MPhA Annual Banquet  
Join us for the closing event of the 111th Annual Convention as we honor outstanding members of the profession and congratulate our leadership.

## Accommodations

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted hotel rates for one of Ocean City's finest resort hotels. *This year's rates are even less than last year's!*

In previous years, the hotel sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! Complete the enclosed reservation request form and mail it directly to the Sheraton Ocean City Resort. All room reservations must be received by the hotel no later than June 1, 1993. Neither MPhA nor the Sheraton can guarantee space availability at these rates after the deadline.

To reserve your room, complete the enclosed green Reservation Request Form and mail it to the Sheraton Resort Hotel at the address listed on the form. For information or questions, call (800) 638-2100.

## Room Rates

Rates are subject to 8 percent room tax. One night deposit is required to guarantee your reservation. Children under 17 stay free of charge in same room as parents. Rooms are available for check-in at 3:00 pm. The Sheraton Ocean City Resort accepts personal checks for deposit only. No personal checks will be accepted after arrival. Credit cards are not accepted for advance deposit. A 72-hour cancellation or change notice is required.

### Guest Rooms (per night)

Single/Double .....	\$120
Triple .....	\$134
Quad .....	\$149
Cabana Suites .....	\$245
Studio Suites .....	\$185

### Condominiums (per week)

With Maid Service .....	\$1,100
Without Maid Service .....	\$ 900





## The Report from Annapolis

*Continued from page 7....*

After SB 692 was killed, there were numerous efforts to "kill" the Pharm.D. program through efforts to add budget language or amend the essence of the defeated measure onto other bills. All these efforts were squelched and the legislative attempts to stop the Pharm.D. program failed.

### House Bill 605

Delegate Cas Taylor sponsored a bill to require full payment from insurers to the providers of durable medical equipment. Under Article 48A of the Insurance Code, this will add a provision which states that a nonprofit health service plan may not require the medical equipment provider to accept less than the full monthly rental amount for each month use is authorized. Furthermore, this authorization must be terminated in writing by both parties. This version was passed in the House by a vote of 129-0. It was sent over to the Senate Finance committee for a hearing, where some amendments were added, and it was given a favorable report. The House concurred with the Senate amendments and both chambers passed the bill.

### House Bill 783

Once again, a bill was introduced to mandate that all drugs prescribed for treatment of an accidental personal injury, an occupational disease, a compensable hernia, or occupational deafness under the Workers' Compensation Act, be dispensed as generics whenever

generics are available. The cost savings to workers compensation insurance funds was ostensibly the driving force behind this bill. The Economic Matters Committee gave the bill a favorable report which was adopted and passed on the floor with a vote of 131-0. Thankfully, this bill sponsored by an uninformed Delegate Hurson, also ran into a barrier in the Senate. It was sent to the Finance Committee where it received an unfavorable report based on our negative testimony and opposition to the bill.

### Health Care Reform

The battle over small employer group health insurance and how to best solve the health care dilemma was a top issue in Annapolis. The Administration cross-filed a bill entitled Small Employer Group Health Insurance Reform. This bill proposed the creation of a board of directors for a reinsurance pool to monitor Small Employer Group Health and apply a community rate standard to all small group health benefit plans. The Economic Matters Committee killed the House version while the Senate Finance Committee rewrote the Senate version entirely. The Senate floor adopted the favorable report given by the Finance Committee, and the first attempt at health care reform passed over to the House of Delegates. Once in the House, the Economic Matters Committee put that version aside and replaced it with a greatly amended House Bill 1359. HB 1359 was eventually passed and became the "sweeping" reform bill everyone has been talking about.

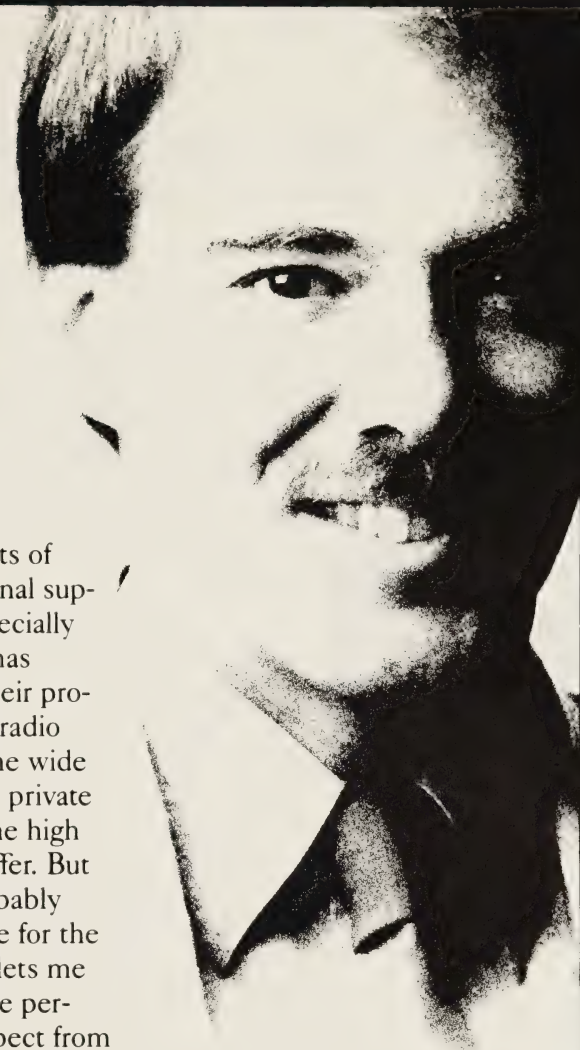
The final bill was positive in a few ways. It will phase out by January 1, 1995 health insurance companies'

practice of not covering individuals with pre-existing conditions, such as hypertension and diabetes. It creates a basic benefits package for both HMO and indemnity insurance that all insurers must offer to small employers of two to 50 employees. That package could potentially be a very lean one. Many mental health, and drug and alcohol health care providers are concerned about the lack of provisions for care in these areas.

The bill creates a seven member commission to be known as the Health Care Access and Cost Commission that will collect and study pricing information from all health care providers in Maryland. The bill states that on or before January 1, 1995, the Commission shall develop and implement a payment system for all health care practitioners. It will also set up practice parameters for medical procedures in an attempt to ensure less overutilization or underutilization of various procedures. After a great deal of cooperation and effort on our part, the Conference Committee members met in total secrecy and came up with this final bill without our input. Our language which was not as potentially harmful to, or controlling of, health care practitioners was disregarded. The adopted language gives the Commission a lot of possible power over health care providers and the fees they charge.

The final outcome remains to be seen. Experts are saying that this is the most far-reaching reform bill to date. However, there are still many unanswered questions about the impact of this bill on pharmacy, or on any other health care provider for that matter. Next month's issue of *The Maryland Pharmacist* will contain an in-depth review of this bill.

*Concluded on page 22....*



**"Over 3,000  
pharmacies  
belong to  
Valu-Rite.  
There must  
be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."

*Scott Rickards*

**SCOTT RICKARDS**  
RICKSAVE DRUG  
NAPLES, MAINE

**McKesson**

# Pharmacists and Compounding

## *Why the FDA's Compliance Policy Guideline Won't Work*

*Shelly Schluter, Executive Director, Professionals and Patients for Customized Care*



The issuance of the Federal Food and Drug Administration's (FDA) Compliance Policy Guideline 7132.16 in March 1992 has caused much confusion and concern in the practice of pharmacy. Although FDA says the document was crafted with the intention of establishing specific criteria for when it will regulate compounding, the guidelines don't meet that objective.

The Compliance Policy Guideline's vague terminology and ill-defined criteria allow individual interpretation, and give FDA the authority to regulate at its discretion. Furthermore, this document was issued illegally and without statutory authority, and therefore should not be supported or endorse by pharmacies.

There are many problems with the Compliance Policy Guideline (CPG), but the biggest is: Congress did not give FDA power over compounded medications. However, because the FDA is now interpreting all compounded drug products to be "new drugs," it is claiming regulatory authority over all compounded medications. And the result is this CPG.

The second biggest problem with the CPG is: it doesn't accomplish its intent - to serve as a guide. A guideline issued by the executive branch of the federal government should precisely and specifically explain what conduct is required and what conduct is prohibited. FDA's CPG does not. The policy used terms such as limited, inordinate, slightly and regularly. How many pharmacists want to be regulated by this statement: "In certain circumstances, it may be appropriate for a pharmacist to

compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available"? This leaves critical questions unanswered. What circumstances? What is a small quantity? What is slightly different? And if a pharmacist doesn't meet their criteria, FDA may deem it appropriate to initiate regulatory action such as "issuing a warning letter, seizure, injunction, and/or prosecution."

Guidelines are issued by a federal agency to accomplish that agency's mandate. The FDA's mandate is to protect the public by ensuring that United States citizens only receive safe and effective drug products. Does the profession of pharmacy threaten public safety? No. The profession of pharmacy has one of the best safety records of any profession in the world and ranks as the most well-respected profession in the country. And even if the profession had produced a significant number of cases - say 10 cases at the retail level in a year - of death caused by gross negligence, the CPG is not crafted to solve any such problems. It never addresses professional procedures or practice standards to better ensure safety. Ultimately, the CPG has nothing to do with FDA's stated rationale: public health.

Every pharmacist in the country should read the CPG and understand that the FDA has no legal authority to issue such a document. Although it has been aimed at compounding pharmacists at the retail level, it is truly a threat to the entire profession. If enforced, the profession of pharmacy would lose its birthright, the cor



literature, reinforces the notion that the human mind is conditioned by virtue of the model or paradigm it embraces to see what it expects to see and to filter out what does not "fit" its paradigm of the world. In computer vernacular, all that "does not compute" falls into the "bit bucket," never to be seen or heard from again.

To make matters even more difficult for an advertiser, the human mind is a finite and relatively simple storage container. It is generally believed that the human mind is unable to deal effectively with more than seven units at one time. In short, the "mental storage bowl" is very small. Yet, brand and pharmacy proliferation have run amok in the past decade. How can anyone remember all the choices? The answer, of course, is that people cannot, and more importantly, will not and do not remember everything.

### **Mental Shorthand and Positioning**

According to Ries and Trout, people have "learned to simplify everything." They organize information on a "mental ladder" that is concise and easy to recall. "*X* is the cheapest in town." "*Y* is the best quality you can buy in shoes." There are rarely more than seven steps in any category's ladder and often far fewer. If a product, service, or outlet was not first on the market, or is not very near the top of the "ladder" already, chances are very good that the mind will pay little (if any) attention to it or not hear any message about it in any meaningful way. The only way to get heard is to dislodge or replace what's at the top of the

ladder, and that can be a real challenge.

Positioning theory explains very nicely why simply advertising will not work. Until we know where our product, service, outlet, or ourselves reside -- if at all -- in the mind of the intended prospect *and* where alternatives to what we offer sit on the mental ladder, the largest advertising budget in the world will have little effect. What counts is what's in the prospect's mind, how the prospect has positioned the offering.

The best way to be heard is to simplify the message and to make it easy to "position" in the mind to achieve a lasting impression. Ries and Trout demonstrated the concept nicely when they looked at the challenge of trying to promote a premium car battery which claimed to be durable. (Hardly an exerting product; hardly a product people spend much time thinking about or remembering.) Sears' brand name "Diehard™" was a phenomenal choice. Short, simple, easy to remember, *and* it says it all. The same can be said for "Duracell™."

### **Positioning Within a Creneau**

In trying to position a product, service outlet (a pharmacy), or yourself where no position exists or competitors have a superior position on the mental ladder, Ries and Trout suggest a French marketing expression, *cherchez le creneau*, which translates to "look for the hole." Looking for the hold demands thinking in reverse, literally to look in opposites. For instance, if all your competitors are large, search for a creneau in the consumer's mind that values small.

"The effectiveness of this approach, of course, depends on the existence of a creneau in the prospect's mind," teaches Ries and Trout.

When everyone is battling to be the "biggest, one-stop, everyday low price outlet," the worst place to position yourself say Ries and Trout -- especially if you are a smaller pharmacy -- is on the same ladder with the "700 pound gorillas." In other words, the toughest sell is to get head to head with "the big guys."

Do creneaus exist in the mind of consumers that would allow a pharmacy to be heard? It is dangerous to generalize, but probably reasonable to believe that creneaus could exist. What about product safety? Is it possible that a drug safety creneau exists in enough consumers' minds? Is it possible that a "pharmacist-controlled, safety-sealed non-prescription drug" is an effective creneau? A size creneau may exist in response to the widespread trend toward "mega-stores." The Volkswagen Beetle, an amazingly successful auto that was "short, fat and ugly," use size very effectively in its long running "Think Small" campaign. Age and gender can be effective creneaus. A number of pharmacies have positioned themselves very well as serving the elderly or young children and teens. A few are achieving success by targeting women only.

A distribution creneau may also exist. Dropping a prescription department into a small high-traffic convenience store is uniquely different than consumers are used to seeing. Yet, it seems to work for hundreds across the country. Professional expertise or authority

may work as a creneau, but only if it's true. For instance, a position around the claim "where physicians shop for their medicines," depends on whether the claim is true and local physicians will verify the claim. But, it can work very well. Ries and Trout are equally blunt concerning a strategy of "trying to be all things for all people." It won't work today! In the product and service arena, an "everybody, everything" position is no position at all, or to borrow from Ries and Trout, "position from nowhere." Their strong advice is to carve out a position in the marketplace, even if that means abandoning a few opportunities elsewhere.

Are there other possibilities? Probably, but they are probably only discernible to the alert and perceptive in a local marketplace. There is much more to learn about this little known (by pharmacists at least) school of marketing theory and practice. The book is well worth an evening's study and maybe even a topic for discussion at a local association meeting. Surely, it is possible to spend time less productively. **R**

### The Report from Annapolis

*Continued from page 18...*

I do not recall any year that was filled with so many ups and downs for pharmacy. Although all our issues went our way except for one, that one issue was our most important. The session was disappointing because we

enlisted the efforts of all our friends in the legislature, MPhA leadership put in many long hours, time away from their families and businesses, to press the legislature for equal access/freedom of choice. Staff devoted valuable resources and we still came up short. I used every effort both traditional and creative to convince Chairman Ron Guns to pass this bill. No one however could change his mind, including the Speaker of the House. What happens when you do everything right and still lose? You evaluate your effort, you evaluate the issue and you evaluate the climate for passage. Then, it is up to the Board, with advice from staff and the Legislative Committee to establish future steps for the profession. **R**



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nerstone of pharmacy - the right to compound drug pursuant to a physician's prescription.

### The CPG - Its Criteria

There are nine criteria listed in the CPG that the FDA may use to determine if enforcement action should be initiated against a pharmacist. Remember - this is not an exhaustive list. FDA reserves the right to add new criteria at any time.

*1. Soliciting business (e.g., promoting, advertising, or using sales persons) to compound specific drug products, product classes, or therapeutic classes of drug products.*

This is a violation of the First Amendment. It also violates the right of a professional to specialize in his or her profession. This would be like telling a doctor that, while he or she can specialize in surgery, the surgeon cannot mention his or her specialization in Orthopedic surgery.

How many pharmacists have ever advertised? Is advertising evil? Is advertising wrong? In fact the courts have invalidated many restrictions on pharmacy advertising. And does the enforcement of this criteria promote the well-being of the public? Does it help to protect the public from unsafe drug products?

*2. Compounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of commercially available, FDA-approved drug products.*

Besides using the vague terms "inordinate" and "essential", this criteria doesn't allow for any exceptions. It just says no compounding of commercially available drugs is allowed. What if a doctor asks for compounded medications because of price or because of allergies to preservatives or dyes?

In effect there is a recent case (Fisons Corporation vs HMM Pharmacy) in which the court said a pharmacist can compound similar dosage forms to a manufactured dosage form, providing the pharmacist stays within the physician-patient-pharmacist triad or relationship.

Does this criteria serve to protect the public? If anything, it would deny patients needed drug products.

*3. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA approved facility.*

How many pharmacists have a file a written assurance that every drug in stock has been made in an FDA approved facility? Furthermore, FDA has no statutory authority to control the source of compounding materials. This is also a clear encroachment on state authority, and it is another not so subtle attempt by the FDA to control compounding by controlling the source of materials.

FDA's inclusion of this criteria is puzzling. History has shown there is no problem of significance in this area. Given the excellent track record, why is this criteria necessary?

*4. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.*

There are two main types of bulk compounding materials. First, there are traditionally well-known compounding materials that have official standards, such as Hydrocortisone Powder and Triamcinolone Powder USP. A pharmacist probably couldn't buy anything other than the USP grades of these materials. There are also the non-traditional compounding materials for which there are so-called official standards. Many of these materials have instead various chemical or food grades. Again, the FDA has failed to make a case that assurances and guarantees are needed.

Again, since no harm has been done, why is this criteria necessary?

*5. Using commercial scale manufacturing or testing equipment for compounding drug products.*

Some so-called manufacturing equipment or testing equipment can easily be adapted to pharmacy compounding. Is this criterion designed to protect the public health?

*6. Compounding inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions.*

The term "inordinate" is again a very vague term. What does this mean? What is too much? Will this



protect the public?

7. *Offering compounded drug products at wholesale to other state-licensed persons for commercial entities for resale.*

When this occurs the FDA has legal authority, because this is manufacturing. Clearly, this practice does not maintain the physician-patient-pharmacist triad and should be stopped. But FDA didn't need to issue this CPG to address this problem.

8. *Distributing inordinate amounts of compounded products out of state.*

"Inordinate" is vague.

If mail-order prescriptions across the state lines are allowed - and they are by the FDA, then compounded mail-order prescriptions are legal. There is no distinction between a compounded prescription and other prescriptions. As long as the triad is in place, mail-order should be allowed for all prescriptions.

Instead, would this criteria really protect the public health? It would possibly deny patients access to pharmacists whom their physicians have chosen.

9. *Failing to operate in conformance with applicable state law regulating the practice of pharmacy.*

This element is unnecessary. Pharmacy is regulated by state law, as enforced by the State Boards of Pharmacy. If a pharmacist is in violation of state law, the state board disciplines that pharmacist - not the FDA. A state law does not warrant intrusion by FDA into the practice of pharmacy. That is precisely what state boards are to regulate.

### CPG - A Wake-up Call

With so much vagueness, its easy to understand why the CPG has caused such problems. And although most of this disorder has been caused by the FDA's sudden and unwarranted attempts to regulate pharmacy, there

is still confusion within the pharmacy profession about the skill and art of compounding, because many pharmacists simply are not familiar with contemporary compounding pharmacy techniques.

After careful analysis of the CPG, it becomes clear that this policy is not a friend to pharmacy. So, who benefits from the implementation of its criteria, if not patients, physicians or pharmacists? FDA benefits, because it achieves the quest of all federal agencies - expounding its jurisdiction. The major beneficiaries, though, are the large drug manufacturers, because the CPG would eliminate compounded drug products. Manufactured drug products would be the only alternative.

Is this the future of pharmacy? **R**

### About the Author

Shelly Schluter is the Executive Director of Professionals and Patients for Customized Care (P<sup>2</sup>C<sup>2</sup>). P<sup>2</sup>C<sup>2</sup> is a non-profit association based in Houston, TX. Its members are pharmacists, patients and physicians committed to preserving the rights of pharmacists and to maintaining regulatory authority at the state level.

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# Continuing Education

## Continuing Education Quiz

May 1993 -- Marketing and Compounding

This month's questions are taken from the articles on national health care reform that appear in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by November 30, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

1. According to Ries and Trout, "To look for the hole", best explains:
  - a. the positioning theory
  - b. mental shorthand
  - c. marketing creneaus
  - d. mental positioning
2. The best advertising message considers both:
  - a. product and service
  - b. product and competition
  - c. strenghts and weaknesses
  - d. profit and costs
3. The pharmacist would be held liable for a PPI violation if he or she:
  - a. failed to counsel the patient
  - b. failed to dispense the PPI
  - c. failed to dispense PPI that warns of adverse effects which are eventually incurred
  - d. improperly filled a prescription
4. Symptoms of delirium is the most common feature of:
  - a. drug intoxication
  - b. physical illness
  - c. mental illness
  - d. elderly patients with brain damage
5. Delirium may be caused by:
  - a. systemic infections
  - b. blood dyscrasias
  - c. electrolyte disturbances
  - d. all of the above
6. The onset of drug-induced delirium is \_\_\_\_\_ while the onset of delirium is \_\_\_\_\_.
  - a. symptomatic; asymptomatic
  - b. slow; abrupt
  - c. abrupt; insidious
  - d. abrupt; slow and insidious
7. According to P2C2, the primary reason the FDA's Compliance Policy Guidelines are inappropriate is:
  - a. guidelines are vague and unenforceable
  - b. guidelines are unapplicable to pharmacists
  - c. criteria guidelines are unnecessary
  - d. FDA is not authorized to enact them
8. The FDA's CPG prohibits all of the following actions, except:
  - a. compounding products that are commercially available
  - b. maintaining inventory for future compounding of prescriptions
  - c. compounding inordinate amounts of drugs in anticipation
  - d. using testing equipment to compound products
9. The FDA has legal authority to act whenever;
  - a. compounded drug products are sold wholesale to others for resale
  - b. state laws are violated
  - c. mail order prescriptions are compounded
  - d. the State fails to act
10. According to P2C2, who will benefit from the CPGs?
  - a. physicians
  - b. patients
  - c. drug manufacturers
  - d. pharmacists

## Pharmacist Forgets PPI -- But No Liability

David B. Brushwood, J.D.



According to the allegations of a recent New York case, a patient was not given a legally required progestin patient package insert by the dispensing pharmacist when the patient dispensed progesterone during the first four months of her pregnancy. She gave birth to a son with a defect of the eye referred to as left-sided microphthalmia.

A malpractice action was commenced against the physician who prescribed progesterone and against the pharmacy that dispensed it. The physician was alleged to have failed to disclose the risks of treatment and to have failed to obtain the patient's informed consent. The pharmacy was alleged to have failed to provide the necessary warning literature as required by applicable federal regulations.

The court noted that the federal regulations require that the drug be dispensed with information concerning the hazards of using progesterone during pregnancy, specifically the increased risk of birth defects in children whose mothers take the drug during the first trimester.

In the mandated leaflet, the potential risk to be warned against as a result of the administration of progesterone concerned "genital abnormalities" in the child. No side effects relating to vision were noted in the warning leaflet.

The lower court dismissed the case against the pharmacy and the appellate court affirmed. There was no liability despite the pharmacy having failed to distribute the warning leaflet required by FDA regulations, because the injury that occurred was not one of the risks noted in the required leaflet. And a pharmacist who fails to distribute the required leaflet is only responsible for the occurrence of those adverse effects that were enumerated in the omitted leaflet.

The case now proceeds against the physician alone, based on the claims of failure to warn and failure to obtain informed consent. **R**

Based On: *Farkas v. Saary*, 1993 Westlaw 62485 (N.Y.App. March 2, 1993)

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# Drug Induced Delirium

## Warning Signs for Long-Term Care Pharmacists

Peter P. Lamy, Ph.D., Sc.D., University of Maryland School of Pharmacy



Acute Mental confusion (transient cognitive disorder, delirium, acute confusional state) as a presenting symptom holds a central position in geriatric medicine.<sup>1</sup> It is a commonly overlooked psychiatric disorder.<sup>2</sup> It is also a common feature of physical illness or drug intoxication which is highly prevalent among the elderly, especially those with brain damage.<sup>3</sup> Indeed, its incidence is highest among elderly persons, in whom it is probably most often missed.<sup>4,5</sup> Yet it is well documented that confusional states are one of the most common and important forms of psychopathology in later life.<sup>6</sup>

As a rule, delirium is caused by extracerebral diseases.<sup>7</sup> Among those would be many frequently encountered in nursing home patients, such as systemic infections, hypoxia, hypoglycemia, electrolytic disturbances, hepatic or renal dysfunction, thiamine deficiency, collagen diseases, and pulmonary diseases. Delirium may also be the result of blood dyscrasias and is not uncommon in post-operative states.<sup>8</sup>

Drug intoxication is a frequent cause as is withdrawal from drugs. A host of drugs has been identified which could cause a drug-induced delirium or other psychiatric adverse drug effects (Table I).<sup>9,10</sup> The OBRA 1987 regulations specifically speak to the danger of drug-induced delirium. Anticholinergic medications (for example antidepressants, antipsychotics, anti-Parkinson drugs, cough and cold preparations, etc.) are among the often prescribed drugs for the elderly. Often, patients receive multiple drugs with anticholinergic

side effects which may tend to cumulate.<sup>11</sup> Side effects of anticholinergics range from discomfort to drug-induced delirium.<sup>12</sup> Elderly patients who commonly receive multiple drugs are at special risk of this additive, cumulative effect.<sup>13</sup>

The onset of drug-induced delirium is usually abrupt; in contrast, the onset of dementia is usually slow and insidious. Definitive symptoms include a clouding of consciousness and lack of attention to any kind of stimuli. One should expect an adverse effect on the sleep-wake cycle, with patients presenting with drowsiness during the day, but hypervigilance at night.

There will be various degrees of memory and orientation impairment, sometimes overlaid by illusions, misinterpretations, and hallucinations. Other patient characteristics in drug-induced delirium may include restlessness, frequent position changes or, in contrast, sluggishness and lethargy. Important is the fluctuation of the state of consciousness. Most of the conditions identified as responsible for delirium will respond favorably to treatment. Drug-induced delirium will respond to withdrawal of the offending agent.

Failure to recognize delirium and to treat the underlying condition or to withdraw the offending agent may have fatal consequences for the patient. This is most likely to happen in the case of the patient with dementia, whose delirium may be misinterpreted as an exacerbation of the dementia.<sup>6</sup>

Consistent application of the criteria presented in DSM-III-R in clinical

practice would help diagnose delirium.<sup>14</sup>

A "risk" approach to the identification of delirium and the patient most at risk to drug-induced delirium has also been proposed.<sup>15,16</sup> R

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## Some Drugs Which May Cause Various Psychiatric Side Effects in the Elderly

Antacids (magnesium)	Ethambutol
Antibiotics	Hydralazine
Anticholinergics	Indomethacin
Anticonvulsants	Isoniazid
Antidepressants	Levodopa
Antihistamines	Levodopa/carbidopa
Antipsychotics	Lidocaine
Anxiolytics	Lithium
Chloroquine	Meperidine
Cimetidine	Methyldopa
Clonidine	Pentazocine
CNS stimulants	Prazosin
Codeine	Prochlorperazine
Cold preparations	Propranolol
Corticosteroids	Sedatives/hypnotics
Cycloserine	Theophylline
Diazepam	Thiazides
Digitalis	Thyroid
Disulfiram	Timolol

**All have side effects which include:** anxiety, confusion, depression, insomnia, psychoses, or undue sedation.

**Adapted, in part, from:** 1) Erman MK, Guggenheim FG: Psychiatric side effects of commonly used drugs. *Drug Therapy/Hospital* 6(11):55, 1981, and 2) Lamy PP: Drug prescribing for the elderly. In Reichel W (ed): *Clinical Aspects of Aging*. Williams & Wilkins, Baltimore, MD, 1983

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## About the Author

Dr. Lamy is Parke-Davis Professor and Chair, Geriatric Pharmacotherapy, Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy, and Professor, Epidemiology and Preventive Medicine, Professor, Family Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201.

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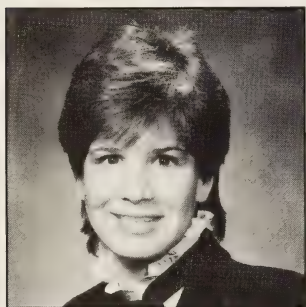
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# *The Maryland Pharmacist*

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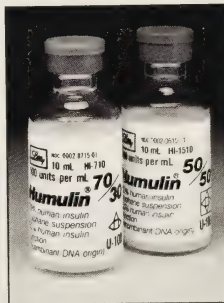
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# The Maryland Pharmacist

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Volume 69

Number 6

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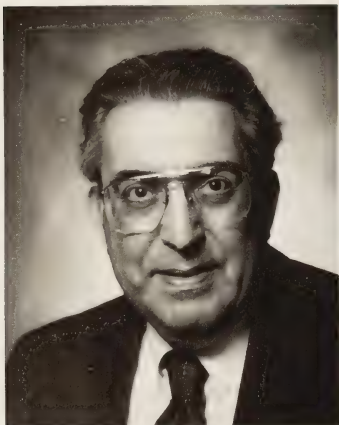
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## President's Commentary

Nicholas C. Lykos, P.D.



This issue of *The Maryland Pharmacist* is being distributed this month to not only our own membership but to all pharmacists in the state.

Some five years ago, the organization's name was changed from Maryland Pharmaceutical Association to the Maryland Pharmacists Association to more accurately reflect who the Association represents. We are the only state pharmacy organization that encompasses all pharmacists in all areas of practices. The Association not only has members in community practice but also in academia, hospital -- outpatient and inpatient, government, industry, long term care -- vendors and consultants, HMO and managed care, and every other possible site where pharmacists are involved.

MPhA is the focal point of pharmacist activity in Maryland. If a pharmacist wishes to express his or her voice, the place to go is the MPhA. The Association, through the trustees and officers elected each year by the membership, are responsible for meeting monthly to address pressing and long term issues facing both the profession and the organization. The House of Delegates, MPhA's democratic policy making body, is the forum where pharmacist express their thoughts and develop the Association's goals and philosophy.

But without members, there is no Maryland Pharmacists Association. Without members, there would be no committees to work on pharmacy issues. Without members, there would be no representation of the profession in Annapolis or Washington. Without members, there would be no organization to fight for the professional and proprietary rights participation.

As you look through this issue, you might be surprised at how much MPhA has done and is doing for the profession. If you've ever asked yourself, "Why should I belong to MPhA?" the answer is in this magazine.

For those of you who are members, I want to personally thank each one of you for your continued support of your state association. I also want to tell you what a great privilege it has been for me to serve as your president this past year.

For those of you who aren't members, I want to take this opportunity to invite you to join the MPhA. On page 30, you'll find a membership application. Since we are in the middle of our dues year, we are extending a special opportunity to all non-members to join the Association for the remainder of 1993 for only \$50. As you can see from this issue, it's a nominal investment that will reap great professional and personal rewards for you. R

# Debunking the Myths

## *Sometimes Perception Isn't Reality*

A classic axiom of advertising is that consumers believe what they perceive. You've no doubt seen evidence of that in your own practice -- the elderly patient who thinks that generics are "bad" because they are less expensive; the patient who believes that 40 mg of furosemide must be "stronger" than 2 mg of bumetanide because it has more milligrams. And no matter how many times you explain that carefully selected generics are just as good as brand name medications or how often you explain that 40 mg and 2 mg aren't always comparable, your patients still choose to believe what they *think* is the truth.

It's hard to imagine that there are pharmacists in Maryland who still cling to their own perceptions about what MPhA is and isn't. Well, it's time that your state pharmacist association shared the reality with you and debunked some of the self-perpetuating myths about the organization.

### *Perception One*

MPhA is dominated by Baltimore area pharmacists and doesn't represent the interests of needs of pharmacists throughout the state.

### *Reality*

Pharmacists who reside in the Baltimore area comprise only 27% of MPhA's membership. MPhA's leadership is an excellent reflection of the geographic diversity of our organization. MPhA has trustees and officers from Garrett, Harford, Cecil, Montgomery, and Allegany Counties as well as from Baltimore County and Baltimore City. In fact, MPhA's House of Delegates changed the organization's bylaws several years ago to ensure that all practice and geographic areas are adequately represented in leadership and committee positions.

### *Perception Two*

MPhA is an organization of store owners and holds little value for employee or staff pharmacists.

### *Reality*

Only 21% of MPhA members are in the pharmacy owner or manager category. That means almost 80% of our pharmacist membership are in staff or employee pharmacist positions.

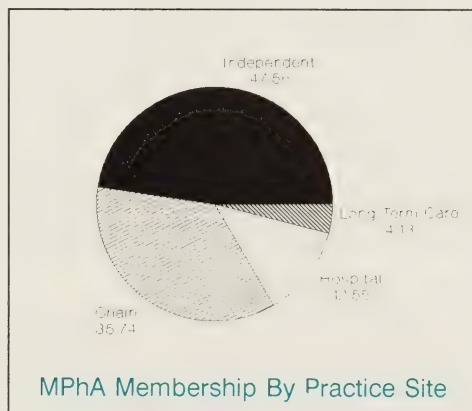
### *Perception Three*

MPhA is only for independent pharmacists.

### *Reality*

Thirty years ago, MPhA's membership was almost exclusively independent pharmacists. Why? Simply because there were far fewer chain or hospital pharmacies than there are today. Long term care and institutional pharmacy practice was still in its infancy. And no one had even heard of clinical pharmacists or HMOs or managed care.

That's all changed now. And MPhA's membership has changed to reflect the profession's growing diversity. Our 1993 membership figures show 47.5% of our members practice in independent community, 35.7% in chain community, 12.5% in hospital, and 4.1 percent in long-term-care settings. If these numbers alone don't convince you that MPhA represents a broad range of pharmacy practitioners, take a look at the pie chart below!



### *Perception Four* MPhA's dues are too high.

*Reality* Pharmacist membership dues in MPhA are only \$100 per year. That's slightly more than a quarter a day investment in your state professional association. Think of the annual dues as an insurance policy that protects your license, your practice and your profession.





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# Ignorance of the Law.....

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# A Year of Accomplishment

## Reports from MPhA's 1992-1993 Committee Chairmen



**Member Services**  
*Ellen Yankellow*

MPhA is your association whether you are a member or not. We are out there each and every day monitoring and influencing what is going on. We are the voice of pharmacy in Maryland. We want you to become an active part of that voice. This year the Member Services Committee started early with our membership drive and it will continue with various promotions through August. In addition our Committee charged each Trustee with the task of phoning twenty members who had not renewed their 1993 membership. A personal invitation was all it took, plus it gave the Board members a chance to talk to the prospective member directly.

The Member Services Committee addressed several other issues besides that of increasing membership. The most important was the creation of the first annual Nathaniel Futrel

Legislative Award. This award was established in conjunction with the Baltimore Metropolitan Pharmacists Association and will be given each year to the MPhA member who has either worked on or for the MPhA Legislative Committee.

Two vital subcommittees of the Member Services Committee is that of the Publications and Convention Committees. We all benefit from the outstanding planning that goes into our mid-year and annual conventions. We have a lot to be proud of in MPhA but I think our monthly journal *The Maryland Pharmacist* and newsletter are second to none. My sincere thanks go out to Beverly Yachmetz, Melvin Rubin, and David Miller for all their work throughout the year.



**Professional Issues**  
*Beverly Yachmetz*

The Professional Issues Committee was developed to review and com-

ment on documents received by the Association which impact on professional aspects of pharmacy practice. There documents may include proposed legislation, regulations, and policy statements issued by national, state, or local organizations.

Over the past year, the Committee was requested to review and respond to six issues. After reviewing, written comments from each Committee member were compiled and a recommendation was forwarded to the Board of Trustees for their discussion and action. The topics reviewed were:

- Whether MPhA should support the retention of OBRA '90's best price provisions
- A document outlining the basic tenets of a publicly funded prescription drug program.
- A request from the Board of Pharmacy for assistance in developing a list of current technology used in pharmacy practice.
- A request from Maryland Medicaid for our recommendations on how patient counseling legislation should be enforced
- NARD's Health Care Reform position paper
- APhA's proposed Code of Ethics

The Committee was composed of pharmacists from varied professional practices. This diversity, combined with the common dedication to pharmacy, provided balance to the reactions and comments. It was a pleasure to serve as Chairman of this committee and I thank all the members for their active participation.





**Third Party**  
*Phillip Marsiglia*

The past year has brought some successes in the third party arena, but unfortunately many more frustrations. The erosion of profitability by deep discount third party programs continues to be the greatest threat to the future of community pharmacy. During the past 12 months the third party committee has met three times as the full committee and more frequently in sub-groups with Medicaid, Blue Cross, Maryland Kidney Disease Program and Express Scripts.

During the summer, several members of the Association met with officials of Blue Cross to review a new pharmacy provider agreement. After considerable discussion, several important changes were made to the agreement with removal of all the objectionable clauses, including a "most favored nations" clause. That clause would limit pharmacy reimbursement from Blue Cross to no more than the lowest level accepted

from any other payer. After a nine month lapse, the agreement was presented to the states pharmacies with the "most favored nations" clause returned. Counsel for the Association has succeeded in having the contract stayed and a hearing before the Insurance Commissioner was held on May 11 to determine the legality of the contract.

The Kidney Disease Program continues to be a source of billing and drug coverage confusion despite discussions with the Program's personnel. The Committee is currently requesting that KDP provide a list of covered products and that they adopt the Universal Claim Form as their billing media.

During the end of 1992 the association met with Baltimore Mayor Kurt Schmoke and representatives of the City of Baltimore to discuss the awarding of their employees' prescription drug program. On two occasions, representatives of the Association testified before the Board of Estimates. Discussions centered on educating the Mayor and Board members about the unique services retail pharmacies provide, about their profit structure and the importance of maintaining a viable businesses in the surrounding community. These efforts directly resulted in the City increasing the proposed reimbursement rate by 25%.

The past year has provided a continuation of our good relationship with Maryland Medicaid. The Medical Assistance/Pharmacy Liaison Committee has met on a quarterly basis and worked together to establish the first on-line claims adjudication system of any state Medicaid program.



**Legislative**  
*Arnold Davidov*

The Committee was given the assignment of passing one piece of legislation this past year as well as monitoring numerous other bills which would impact our practice. Our major charge was to obtain equal access to all HMO pharmacy benefit networks for pharmacists. In addition to this, the Legislative Committee analyzed 56 separate pieces of proposed legislation and recommended positions to the Board of Trustees.

While MPhA's efforts to pass consumer access/freedom of choice legislation in total was not successful, we were able to obtain language that would require HMO's to notify the Association whenever they plan to alter their pharmacy benefit network. This modified version, secured at the last minute by the Committee, will enable your Association to notify pharmacists throughout the state about potential changes in networks. This will allow pharmacists to actively

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pursue contracts that heretofore were negotiated behind closed-doors with select pharmacy groups.

In addition, the bill also prohibits the "application blackmail" that many HMO's have resorted to -- Maryland law now prohibits any HMO from charging a pharmacy provider an application fee. This was a direct response by MPhA and legislators to the unscrupulous tactics of Health Plus.

While we are disappointed that we did not achieve our goal, the legislative process is an ongoing one. Though we didn't win 100% of this issue, we have succeeded in drawing strong attention to the HMO/pharmacy exclusion problem. We also believe that our work has put the HMO community on notice -- pharmacy will no longer tolerate "closed door" negotiations that are perceived in Annapolis as an open process. Hopefully the strong background work done by the Committee and the heavy grassroots lobbying effort by MPhA and its members will enable us to secure this legislation in the future, should it continue to be necessary.

Delegate Donald Elliott from Carroll County introduced legislation modeled after a Wisconsin statute that would have prevented discriminatory prescription pricing by pharmaceutical manufacturers. Under this bill, a violation would have resulted in treble damages.

MPhA's testimony included specific examples of discriminatory prices charged by manufacturers to different pharmacies *who are in direct competition with each other*. Because of the complexity of the issue, the House Economic Matters Committee

referred this to a summer study to perfect the language of the bill. MPhA will continue to support this effort.

Much attention was focused during the session on the health care reform package. MPhA will need to monitor the new Health Care Cost Commission closely to ensure that pharmacist services are included and fairly compensated and that prescription products are not the only portion of a "pharmacy benefit." This will take a great deal of time and effort.

I recommend that MPhA form a Task Force on Health Care Reform with representatives from the Legislative, Third Party, and Professional Affairs Committees to act as a "think tank" for state and national health care reform efforts. A broad representation of practice sites, as well as professional experience, will enable MPhA to most effectively protect the interests of the profession and our patients.

There were several pieces of legislation affecting durable medical equipment providers. Since many pharmacies are involved in providing these products to patients, the Committee believed that close monitoring and lobbying activity were warranted.

One bill MPhA supported was House Bill 605. This legislation prohibits an insurance company or third-party program from reimbursing the pharmacy or DME provider for only the cost of the DME as opposed to the payment of monthly rental. Some insurers were attempting to circumvent the capital investments made by DME suppliers by refusing to pay the monthly rental after a

certain number of months. House Bill 605 was passed by both the House and Senate.

Another bill that MPhA tracked was Senate Bill 514. This bill would have required all "home medical equipment providers" to register with and abide by regulations set by the Department of Health and Mental Hygiene. According to the definitions in the bill, "home medical equipment" could include such common pharmacy items as glucose monitoring machines and blood pressure monitors as well as walkers, crutches, canes, etc.. The Committee believed that whenever regulation of a group is sought, it is generally done so in order to exclude some members of the group. Because of the far reaching ramifications on the profession, MPhA first amended pharmacists and pharmacies out of the bill. After that, working under the philosophy that additional regulation of any health care group is unnecessary, we worked to kill the bill entirely. The bill was finally defeated by the House Environmental Matters Committee.

In conformity with MPhA's House of Delegates' position to support the University of Maryland School of Pharmacy's move to an all-Pharm.D. program, the Legislative Committee opposed two pieces of legislation that would have prevented the program from going forward. This legislation would also have prevented the transfer of current second-year pharmacy students into the optional Pharm.D. program, an unintended but serious side effect of a poorly worded bill.

The University system, the School of Pharmacy, and the Higher Education Commission were



responsible for convincing the legislators that micro-managing a professional curriculum was a bad legislative precedent. MPhA lent support to their efforts through our Legislative Fax Alert network which encouraged individual pharmacists to voice their opinions about the all-Pharm.D. program to their representatives.

On behalf of the Committee, I commend the MPhA staff and our lobbyist Robin Shaivitz and her assistant Caren Silverberg for all the time and effort put into a complex and challenging session. We came away from this session with several improvements on our legislative efforts. These include the establishment of our Legislative FAX Alert network, a well researched study of the impact of HMO pharmacy network exclusions (the only one of its kind in the nation), and strong cooperation between MPhA and members of MACDS.

Without the immense amount of time and effort spent by the individual members of the MPhA Legislative Committee, we could not have accomplished as much as we did. Special thanks goes to Ernie Testerman, Jim Tristani, and Ellen Yankellow for the willingness to rearrange their schedules to meet with legislators and attend hearings. I would also like to thank pharmacists Jill Molofsky, Mark Levi, Howard Klein, Butch Henderson, Murhl Flowers, Bob Kabik, Gary Wirth, Leo Mallard, Wally Szot -- each of these MPhA members took time out from their practices to actually attend hearings or meetings with legislators in Annapolis. Also, each one of you who called, wrote or met with your

delegates or Senators deserve a "thanks." Pharmacy is recognized in Annapolis as being one of the most effective groups in rallying support from its members. That reputation is due to unstinting devotion by our volunteers.



**Budget & Finance**  
*Ronald Sanford*  
*Chairman*

The primary function of the Budget and Finance Committee is to prepare the operating budget for the Association for the calendar year. The Committee is appointed by the President, following the Annual Convention in June. The Committee must present a budget to the Board of Trustees for approval prior to the commencement of the following calendar year. In this manner, the newly elected President and Board will work within the guidelines set forth in the budget established in the previous year for the first six months

of their terms of office and then within the guidelines of the budget they approved for the remaining six months. This method offers a balance of budgetary control.

The Treasurer, as chairman of the Committee, serves as the "watchdog" over the finances of the Association and attempts to guide the Board in working within the approved budget. I am pleased to report that for the calendar year 1992 the Association budget process worked well. A realistic budget was approved; income goals were achieved and in several categories significantly exceeded. Expenses were maintained within acceptable limits. Where some expense categories seemed out of line, comparable income categories offered acceptable offsetting of expense overages. Despite the sagging economy, we completed 1992 carrying forward some unspent reserves for future unexpected expense. **R**

# Following Through On '92

*A Report from MPhA's Executive Director*

David G. Miller, P.D.



Each year, it is my responsibility to report to the membership and the House of Delegates those actions taken by the MPhA Board of Trustees and its standing, special and ad-hoc committees towards fulfillment of the policy and position statements adopted by the MPhA House of Delegates.

At the 1992 MPhA Annual Convention, the House of Delegates adopted six resolutions, referred one resolution to the Constitution and Bylaws Committee, and tabled one resolution during its debate on June 17. Each resolution is reproduced below, along with a brief overview of what action was taken to implement the resolution.

#### **Mandatory AIDS Testing**

The Maryland Pharmacists Association opposes mandatory HIV testing of Department of Labor Joint Advisory Notice HBV/HIV Category II and Category III pharmacists.

Mandatory AIDS testing was one of the issues discussed in depth by the American Pharmaceutical Association. Using this resolution as a foundation, MPhA's delegates to the APhA voted in favor of a national pharmacy policy opposing mandatory HIV testing of pharmacists. While MPhA's resolution limits the group of pharmacists, APhA's policy went further and opposed testing of all pharmacists in favor of voluntary testing.

#### **All Pharm.D. Program**

The Maryland Pharmacists Association reaffirms its position of support, as adopted in June 1990, for the establishment of the Pharm.D. degree as the sole entry level degree offered by the University of Maryland School of Pharmacy.

#### **External Pharm.D. Degree**

The Maryland Pharmacists Association supports a University of Maryland School of Pharmacy external Pharm.D. program for existing practitioners that gives significant credit for years of practice, that the program be based on continuing education credits earned and programs attended, that the program must be easily accessible to all pharmacists wanting to earn the degree, and that the cost of the program must be very reasonable.

MPhA was instrumental in helping the University of Maryland defeat legislation that would have prevented or delayed the implementation of the all-Pharm.D. program at Maryland. Using the Association's *FAX-Alert* networking system, pharmacists around the state were notified and encouraged to express their opposition to any attempt to derail the all-Pharm.D. program. President Nick Lykos, who served as the first chairman of the School of Pharmacy's Pharm.D. Transition Advisory Committee, recommended more than 40 MPhA members to the School's transition committees.

MPhA is strongly represented on those committees working on the external Pharm.D. program including the Prior Learning Assessment Evaluation Committee which looks at how much credit pharmacists should receive for their professional experience and continuing education activities. The Association will continue to follow the external Pharm.D. program closely to

ensure that every pharmacist in Maryland who wants to pursue a Pharm.D. degree has the opportunity to do so.

#### **Out-of-State Licenses**

The Maryland Pharmacists Association seek legislation to require out-of-state pharmacies delivering prescription drugs to Maryland citizens within the state to obtain a pharmacy permit from the Maryland Board of Pharmacy and to adhere to the pharmacy laws and regulations of the State of Maryland.

MPhA's Legislative Committee contacted the Board of Pharmacy to ask their assistance in initiating legislation that would require out-of-state pharmacies to obtain Maryland pharmacy permits. The Board has indicated their willingness to assist MPhA in this legislation and the Committee will work to introduce legislation in the 1994 Legislative Session.

#### **Recycling of Rx Containers**

The Maryland Pharmacists Association should solicit a resolution by the national pharmacist and pharmaceutical manufacturing organizations that they phase in procedures to facilitate recycling of pharmaceutical products' bottling and packaging because we care for our patients and we should also be able to show our care for our environment.

In follow-up to this resolution, MPhA is submitting this topic to its national affiliates NARD, APhA and ASCP for consideration by their practice committees. We will continue to press for their support.

#### **Equal Access to Pharmacy Care**

MPhA supports the concept of equal access for pharmacy care and that the MPhA continues to support the passage of such legislation.

As outlined in the May 1993 issue of *The Maryland Pharmacist*, MPhA worked to pass legislation that would mandate equal access for HMO pharmacy benefit recipients this past legislative session. Although the final edition of the bill only requires Maryland HMO's to notify the Association whenever they propose to change their pharmacy benefit contracts, it does give MPhA the ability to notify all pharmacists in the state. We believe that this will at least open some of the "closed door" activities of some HMO's and hopefully will enable the state's two pharmacy buying cooperatives and our chain pharmacy operations departments to present service and participation proposals.

In addition to working on a state level, the MPhA Professional Issues Committee and the Board of Trustees have reviewed and endorsed health care reform position papers from APhA and NARD. These position papers,

presented to the Clinton Administration, insist on an equal access to pharmacy services based on a series of quality care criteria.

#### **Resolutions Committee**

The House Resolutions Committee shall:

- 1) Review, discuss, and recommend a position to the House of Delegates for each resolution sent to the House Resolutions Committee by any active member.
- 2) The Committee may recommend one of the following positions for a resolution: adopt, defeat, refer to committee or table. The Committee may also request the withdrawal or redrafting of any motion. In the event that the member submitting the resolution declines to withdraw or edit the resolution, the Committee shall recommend a position on the resolution as presented.
- 3) The House Resolutions Committee is empowered to draft resolutions and recommend positions on those resolutions it creates. The House Resolutions Committee is also empowered to determine the order in which resolutions shall be presented to the House of Delegates after consultation with the Speaker of the House.

These policies shall be incorporated into the next revision of the Maryland Pharmacists Association's bylaws.

#### **Resolution -- Delegates At Large**

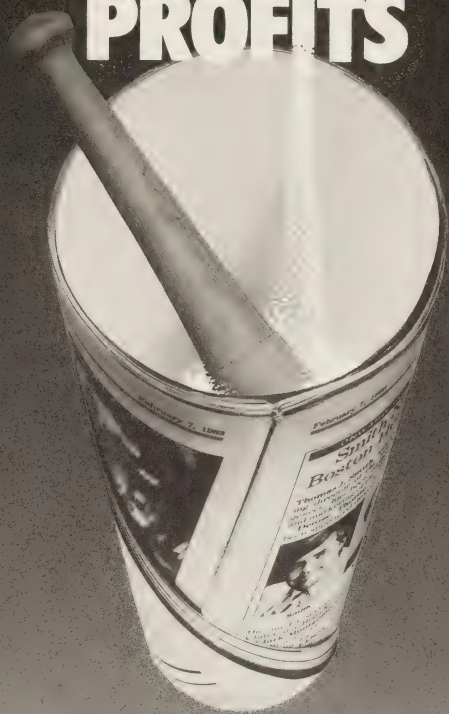
MPhA's House of Delegates' limit of twenty at-large delegates and their manner of appointment is hereby rescinded; and, any active member of the Maryland Pharmacists Association is entitled to serve as an at-large delegate, with full rights and privileges as a delegate as outlined in the MPhA Bylaws, provided that they register with the Secretary of the House of Delegates at least one (1) hour before any meeting or session of the House of Delegates; and, this policy shall be incorporated into the next revision of the Maryland Pharmacists Association's bylaws.

These two resolutions were not adopted by the House of Delegates; both were subsequently sent to the House Constitution and Bylaws Committee. The spirit of the resolution addressing the proper functioning and purpose of the House Resolutions Committee was shared with the 1993 Resolutions Committee and incorporated into their Committee process and policies.

The resolution to replace the current at-large delegate appointment process with the "one member, one vote" alternative was discussed by the Constitution and Bylaws Committee. Although the House of Delegates voted *against* this concept in the 1991 bylaws revision process, the Committee believed that "one member, one vote" was the preferred method for promoting the rights of the Association's members to determine their organization's policies. Their recommendations will be reported to the House of Delegates at the 1993 Annual Convention. **R**



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# What Does MPhA Stand For?

## *A Compilation of MPhA Policy Statements*

*Ernest Testerman, Speaker, MPhA House of Delegates*

*Alisa Billington, Vice Speaker, MPhA House of Delegates*



Each year, the Maryland Pharmacists Association's House of Delegates debates member submitted resolutions. Once passed, these resolutions form the foundation of the Association's policies. These policies serve the members in several ways. They direct the Board of Trustees as they evaluate, approve and institute new programs. They enable the Association to respond to local, state and national initiatives. Most importantly, these policies let those outside the profession know just where Maryland pharmacists stand on different issues.

So that you can best understand what MPhA stands for, we are publishing this compilation. Some policies are clearly outdated or no longer necessary; however, they do show an evolution of both the profession and the Association.

### **Fax Machines**

Adopted 1989

MPhA will cooperate with the Board of Pharmacy to establish regulations on the use of FAX machines.

### **USP/NF**

Adopted 1989

MPhA recommends that USP consider combining the USP/NF with the USP-DI into a single publication.

### **Drug Product Selection/Insurance**

Adopted 1987

MPhA supports the concept that pharmacists should have the final authority to determine the ultimate version of the prescription drug to be dispensed to permit consistent drug

therapy in the best interest of the patient, regardless of changes in that patient's prescription drug coverage.

MPhA takes appropriate action to urge insurance companies to grant this authority to pharmacists.

### **Veterinarian Dispensing**

Adopted 1988

MPhA supports the concept that dispensers of veterinary medicines should meet the same reasonable requirements that pharmacists or other authorized dispensers in Maryland are required to meet, specifically with regard to childproof containers, labeling, and record keeping.

MPhA supports appropriate regulatory or legislative action to control dispensing of veterinary medications.

### **Pharmacy Ownership**

Adopted 1988

MPhA shall initiate a task force to investigate the issue of pharmacy ownership laws and regulations.

MPhA supports legislation that prohibits prescribers from direct or indirect profit from a relationship with a pharmacy.

### **Mail Order**

Adopted 1986

MPhA will continue its efforts to obtain regulation of out-of-state mail order prescription drug programs and pharmacies for the protection of the public health.

MPhA will continue its efforts to educate the public on the disadvantages of mail order prescription drug programs and the benefits of contemporary community pharmacy practice.

Adopted 1984

MPhA condemns the practice of mail order prescription drug services as being unprofessional.

MPhA shall develop a public education program to alert consumers to the advantages of community pharmacy practice and the hazards of mail order prescription drug services.

#### **Physician/Prescriber Dispensing**

Adopted 1985

Any system which encourages physician dispensing of prescription drugs for profit is condemned as contrary to good personal and public health.

MPhA shall introduce resolutions to regulate authorized prescribers who dispense prescription drugs for human consumption for profit.

#### **Handling of Antineoplastics**

Adopted 1984

MPhA urges all employers to properly protect employees from the hazards of handling antineoplastics agents by following the guidelines recommended by the American Society of Hospital Pharmacists and other health care organizations.

#### **Lie Detector Tests**

Adopted 1984

MPhA opposes any attempt by any employer to use the results of lie detector tests as a basis for employment or denial of employment of professionals.

#### **Drug Product Selection**

Adopted 1984

MPhA encourages Maryland prescribers to indicate in their own handwriting on a case by case basis the extent of drug product selection.

#### **Legible Prescriber Information**

Adopted 1984

MPhA will seek legislation to require that the following information be legibly printed on all prescription orders: location or exact address of prescriber; telephone number where prescriber or his agent can be reached; written and printed name of prescriber with financial penalty

imposed if this information is omitted.

All Maryland pharmacists shall assist the Association by forwarding the original prescriptions (excluding Schedule II prescriptions and patient identity) to the Association to produce a visual record of the extent and severity of the problem for the members of the Maryland Legislature.

#### **Special-Use Pharmacies**

Adopted 1984

MPhA supports legislation which permits special-use pharmacies to meet special patient needs (ie. home-bound, nursing homes, correctional institutions, radiopharmaceutical patients).

#### **Pharmacists as Patient Educators**

Adopted 1983

MPhA shall encourage the use of patient information systems which include reference to the pharmacist as a source of information on drugs.

#### **Board Disciplinary Actions**

Adopted 1983

MPhA shall form an advisory group or use an existing committee to assist pharmacists who are "subject of complaint" in a Board of Pharmacy action if possible, and that this service be made known to MPhA members.

#### **Unauthorized Refills**

Adopted 1983

MPhA shall pursue legislation to allow the pharmacist to exercise his professional judgement to dispense needed medication of a refill, after an attempt has been made to obtain authorization from the prescriber, for a 72 hour period of time necessary until the prescriber will be available.

#### **Sentences for Armed Robbery**

Adopted 1982

MPhA urges mandatory sentences for persons convicted of armed robbery involving controlled substances.



### **Lagman Receives Kaufman Award**

Abigail Lagman, a 1993 graduate of the University of Maryland School of Pharmacy, was selected by the MPhA Past Presidents Council as this year's recipient of the Harry D. Kaufman Award. Given annually, the Kaufman Award recognizes exemplary service to either the community or the profession by a pharmacy student. In addition to serving her classmates as president of the Academy of Students of Pharmacy -- Maryland Chapter, Abigail recently completed a one-year term as an MPhA student Trustee.



### USP-DI

Adopted 1980

MPhA recommends the USP-DI serve as a primary source of drug dispensing information in Maryland

### Pharmacist's Prescribing Act

Adopted 1979

MPhA shall appoint a committee to investigate the feasibility of a Pharmacist's Prescribing Act.

### Prescription Transfers

Adopted 1978

MPhA supports legislation or regulation changes permitting the transfer of prescription information between pharmacists for the purpose of refilling prescriptions.

MPhA supports the establishment of proper controls over this procedure to prevent unauthorized use of prescription medications.

### Third Class of Drugs

Adopted 1992

MPhA seek legislation to mandate a phase-in "Sale by Pharmacy Only" period for all prescription legend medications which change to OTC status.

### Standards of Practice

Adopted 1991

MPhA shall define the standards of practice of pharmacy in the state of Maryland; and,

MPhA will work with the Maryland Society of Hospital Pharmacists and other pharmacy groups so that the standards of practice accurately reflect pharmacy's varied practice areas; and, that the MPhA make a standards of practice document available to every pharmacist in the state.

### Mandatory Patient Counseling

Adopted 1991

MPhA opposes any regulatory or legislative activity that mandates patient counseling by pharmacists; and that the MPhA pursue the State's recognition of the standards of practice, developed by the Association, as sufficient to meet the requirements of the Federal Omnibus Budget Reconciliation Act (OBRA) of 1990.

### Smoke Free Pharmacist

Adopted 1991

MPhA strongly recommends and encourages that all pharmacies be smoke-free and that implementation of this policy be accompanied with appropriate public education programs, including the conspicuous posting of signs.

### Prescription Pad Advertisements

Adopted 1991

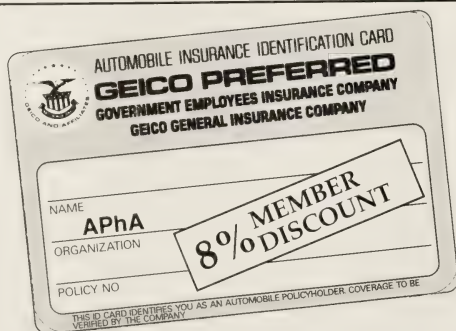
MPhA seek legislation that would prohibit the use of prescription pads by prescribers that include either the advertising of a manufacturer of pharmaceuticals or the name of a drug product on the prescription pad or included within the packet of pads.

### *Pharmacist Education Policies*

### Pharm.D. Degree

Adopted 1990

MPhA supports the move to an all Pharm.D. program by the University of Maryland School of pharmacy.



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MPhA will support the requirement that the School of pharmacy produce a program in which external Pharm.D. degrees can be obtained by interested B.S. practitioners based upon continuing education programs, experience in practice and other mechanisms where credits can be earned outside the traditional classroom model.

Adopted 1983

MPhA shall form a Task Force Committee including all areas of practice to consider the appropriate entry level degree into the profession.

This committee shall explore methods for current B.S. pharmacists to attain this same degree.

#### **Use of Calculators on the NABPLEX**

Adopted 1991

MPhA requests the Board of Pharmacy to propose this issue to NABP again; and that since NABPLEX charges nearly \$250 to take the exam, that the NABP shall supply a simple calculator to be utilized by the examinees.

Adopted 1989

MPhA supports the submission by the Maryland Board of Pharmacy to the NABP of a change in their policies to allow calculators to be used on the NABPLEX exam.

#### **Home Study Programs**

Adopted 1989

MPhA requests that the University of Maryland School of Pharmacy establish home study programs as the basis for establishing certificate programs in different pharmacy specialties and training.

The Association requests that the school consider using home study programs as the basis for establishing certificate programs in different pharmacy specialties and training.

#### **Non-Traditional Graduate Degrees**

Adopted 1981

MPhA supports the establishment of programs in which graduate degrees could be obtained in a home study

and/or part-time classroom setting.

An ad-hoc committee shall be appointed to explore such a program with the University of Maryland School of Pharmacy or any other accredited school of pharmacy which would support such a program.

#### **Continuing Education**

Adopted 1991

MPhA, by legislative action, shall change the mandatory continuing education requirements to eliminate the exemption for newly licensed pharmacists so that all pharmacists must earn continuing education credits immediately upon being licensed.

Adopted 1986

MPhA will seek a method for publishing a compilation of continuing education opportunities available from the major manufacturers for the use and benefit of Maryland Pharmacists.

Adopted 1984

MPhA shall actively pursue through legislative action the institution of continuing education for pharmacists as a requirement for re-licensure.

Adopted 1968

MPhA shall make every effort to implement a state-wide continuing education program as a pre-requisite for re-registration.

#### **Professional Experience Program**

Adopted 1968

MPhA recommends to the School of Pharmacy and the State Board of Pharmacy, immediate implementation of a preceptorship program for the pharmacists of the State of Maryland

The students be assigned to these preceptors as a part of their formal school curriculum.

#### *Third-Party Issues*

#### **Medi-Gap Insurance for the Elderly**

Adopted 1990

MPhA will collect information from its members regarding the pharmaceutical benefits of Medi-Gap type

insurance policies offered to Maryland's elderly.

MPhA will inform the Insurance Commission of its findings and assist in the pursuit of legislation that would regulate such policies, if necessary

#### **Telecommunications Charges**

Adopted 1989

MPhA seeks that all telecommunications line charges for claims adjudication under the prescription drug provisions of the Medicare Catastrophic Coverage Act of 1988 be borne by the Medicare program rather than participating pharmacies.

#### **Third-Party Oversight**

Adopted 1989

The scope of the Third-Party Committee of the association be expanded to oversee all third-party related activities and issues.

The Committee is to inform the membership of third-party provider activities in Maryland and to report and recommend actions to the Board of Trustees monthly.

#### **Reimbursement for Professional Services**

Adopted 1989

MPhA seeks reimbursement from third-party payers for professional pharmacy services.

MPhA supports the concept that pharmacists should be reimbursed for professional pharmacy services separately from dispensing fees.

#### **Managed Care for Medicaid Recipients**

Adopted 1988

MPhA opposes assignment of Maryland Medicaid recipients to managed health care systems with closed pharmacy agreement or agreements.

#### **Benefit Administrators**

Adopted 1985

MPhA shall conduct a statewide educational symposium for the administrators of health care plans to discuss health care containment strategies that emphasize freedom of

choice.

### **Third Party Committee**

Adopted 1980

The membership of the Third Party Committee of the MPhA shall be expanded and the Chair of said Committee be, and is hereby, urged to select one person from each affiliated local pharmacy group throughout the State for membership on said Committee.

The functions and responsibilities of said Third Party Committee be enlarged and elaborated upon and specifically defined to the end we all desire - adequate compensation for services rendered.

### **Third Parties**

Adopted 1978

MPhA shall set up and distribute necessary guidelines for pharmacists and pharmacies to follow when audited by any third party provider.

### **Timely Notice**

Adopted 1992

MPhA seek by regulation and legislation a requirement that all insurers, HMOs, third-party administrators, Medicaid and any other program that provides pharmaceutical benefits must notify that program's participating pharmacies of changes to the program's rules and requirements at least 30 business days in advance of the proposed change; and,

Legislation and regulation should require that if the program fails to provide such notice, any claim submitted from the date of notice until 30 business days after the notice must be honored and paid in full under the program's guidelines in place before the date of notice.

### **Differential Pricing**

Adopted 1989

MPhA opposes differential pricing and will work toward repealing the Robinson-Patman Act by exploring all avenues of possible involvement.

### **Discriminatory Sales of Pharmaceuticals by Non-Profit Organizations through For-Profit pharmacies**

Adopted 1986

MPhA seeks and supports the restatement or modification of the Nonprofit Institutions Act exemption from the Robinson-Patman Act and such other legislative changes as are necessary to restore fair competition.

### **Discriminatory Pricing**

Adopted 1986

MPhA supports the concept that pharmaceutical manufacturers charge a single uniform price to all purchasers of pharmaceuticals under the same conditions.

### **New Drug Information**

Adopted 1986

MPhA requests that the pharmaceutical manufacturers inform pharmacists as well as physicians on emergency matters such as recalls and changes in prescribing and/or labeling of their products.

MPhA also requests that the pharmaceutical manufacturers promptly provide pharmacists with drug information on any new products which are released.

### **Drug Samples**

Adopted 1986

MPhA supports the elimination of all drug sampling and replace it with a coupon issued by the manufacturer for a starter dose that would be dispensed by the pharmacist in the same manner as any physician's prescription.

The manufacturer offering the coupon would reimburse the pharmacist for the product dispensed, plus the pharmacist's dispensing fee.

### **Parenteral Drugs**

Adopted 1980

MPhA encourages manufacturers to provide pharmacists information on the effects and treatment of inadvertent contact of parenteral drugs on eyes, mucous membranes and skin.

### **Distribution of Information**

Adopted 1989

MPhA again requests that all pharmaceutical manufacturers and distributors, and McNeil Laboratories in particular, make all information on any particular drug available to both physicians and pharmacists at the same time.

### **Pharmaceutical Manufacturers**

Adopted 1981

Prescription drug manufacturers shall be informed that Maryland pharmacists are dissatisfied with prescription drug manufacturers that set a time limit and/or decrease of credit on returns of such prescription drugs.

### **Pharmacist Committee Members**

Adopted 1990

All pharmacist members of all standing and ad-hoc committees be active, dues-paid members of the Association, except when otherwise authorized by the By-laws or special provisions by the Board of Trustees.

This provision shall take effect for the committees being formed for the 1990-1991 Association year.

### **Past Presidents Council**

Adopted 1989

MPhA will establish a Past Presidents Council to act in an advisory capacity to the Board of Trustees.

Any past president in good standing may elect to serve on the council.

The immediate past Chairman of the Board of Trustees will ordinarily serve as Chairman of the Past Presidents Council.

### **Maryland Pharmacist Week**

Adopted 1990

MPhA will officially recognize and promote "Pharmacist Week" as an annual joint activity between itself and the Maryland Society of Hospital Pharmacists.





## Bradley Elected As Trustee

Lynette Bradley of Greenbelt, MD has been elected to a three-year term on the MPhA Board of Trustees. Lynette comes back to the Board after having served in 1991 as the student Trustee. A second-generation pharmacist, Lynette plans to return part-time to pharmacy school this fall to pursue an advance degree in pharmacy administration.

## Resolution Follow-Up

Adopted 1985

MPhA shall submit an oral and written report to the membership at the following annual meeting that states the steps taken by the Association to satisfy the intent of each resolution.

This report shall be published in *The Maryland Pharmacist* as part of the convention report.

## Name Change

Adopted 1985

The name of the association shall be the Maryland Pharmacists Association and that the Officers and Board of Trustees be instructed to take any necessary legal steps to complete this change of name.

## Oral Committee Reports

Adopted 1983

All oral committee reports presented to the House of Delegates shall be limited to ten minutes.

## Rehabilitation Committee

Adopted 1982

MPhA shall form a "Rehabilitation Committee" to study methods for detection, counseling and support services for chemically impaired pharmacists.

## Convention Scheduling

Adopted 1981

MPhA discourage the scheduling of conventions or other official functions during the NABPLEX exam or other student required activities.

## Smoking

Adopted 1981

MPhA shall forbid smoking at all business functions.

## P.D. Designation

Adopted 1981

MPhA, representing the pharmacists in the State of Maryland adopts the professional designation "Doctor of Pharmacy" with its resultant abbreviation "P.D."

This designation will replace the previous designation "Registered Pharmacist", R.Ph. and shall be used in the same manner. It is not an academic degree, and it is not an endorsement for any particular pharmacy education degree.

## APhA Affiliation

Adopted 1980

After careful consideration of the "Statement of the APhA Board of Trustees on Affiliation", that the MPhA petition the American Pharmaceutical Association for status as an "Affiliated" state under the terms of the statement.

## MPhA and MSHIP

Adopted 1980

MPhA and Maryland Society of Hospital Pharmacists seek ways to cooperate and combine efforts compatible with the mutual objectives of each organization; particularly in the areas of conventions and publications.

## Continuing Education Programs

Adopted 1991

The number of live continuing education programs offered by the MPhA should be increased from two to six per year; and, that each program would be held in a different geographic area of the state and be non-repetitive; and, the programs would be open to all pharmacists statewide and, whenever possible, be held jointly with local pharmacy associations; and, that at each program a segment would be included that informed all pharmacists in attendance the accomplishments of the Association and the goals towards which it is working.

## ASCP Affiliation

Adopted 1991

MPhA pursue "Affiliated Organization" status with the American Society of Consultant Pharmacists.

## DMSO

Adopted 1981

The pharmacist shall become familiar with DMSO and be prepared to provide consumer information where appropriate on traditional forms of alternative therapy.

## Legalization/Decriminalization of Controlled Dangerous Substances

Adopted June 1990

MPhA states publicly its opposition to the legalization/decriminalization of controlled dangerous substances.

MPhA will participate in any forums, legislative initiatives, or other discussions regarding the issue of legalization/decriminalization of controlled substances.

# Pharmacists Helping Pharmacists

Experts believe that 10% of Americans suffer from some form of chemical or alcohol problem. The disease of dependence knows no boundaries -- rich or poor, educated or illiterate, black or white are all victims.

Those who suffer from dependency shouldn't be ignored.

If you or some you care about is suffering with an alcohol or drug problem, help is available from friends who care -- the Pharmacists Rehabilitation Committee of Maryland.

For a free, confidential consultation call the Pharmacists Rehabilitation Committee at (410) 727-0746 or 706-7513

**Pharmacists Rehabilitation Committee**  
**410 727-0746 or 410 706-7513**



## **Anabolic Steroids**

Adopted June 1989

MPhA will work with other professional practitioner societies to improve the control of the distribution of anabolic steroids.

## **Funding Public Relations Program**

Adopted June 1989

MPhA in cooperation with Maryland Society of Hospital Pharmacists will investigate the establishment of a statewide public relations campaign.

The Association will seek ways of funding such a campaign.

## **Tracking CDS prescriptions**

Adopted June 1988

MPhA will work with the Division of Drug Control to establish a method of tracking prescriptions of CDS.

## **AIDS Prevention Programs Among IV Drug Users**

Adopted June 1988

MPhA supports only programs of needle and syringe distribution to IV

drug users that use community pharmacies and pharmacists as distribution sites.

## **AIDS/Condoms**

Adopted June 1987

MPhA supports and encourages the distribution, promotion and advertisement of condoms.

## **CPR Certification**

Adopted June 1987

MPhA urges all pharmacists to be CPR certified by the American heart Association or the American Red Cross.

MPhA shall offer a CPR certification/recertification course at least once a year to all Maryland Pharmacists.

## **Advertising of CDS**

Adopted June 1986

MPhA seek methods to end prescription price advertising of all Controlled Dangerous Substances as inappropriate and contrary to the good of the

public health.

## **Alcohol and Medications**

Adopted June 1983

MPhA recommends that a warning statement such as "please ask your pharmacist if you have any questions concerning the possible interaction of alcoholic beverages and your medication" be placed in all pharmacy sponsored advertisements for alcoholic beverages. **R**

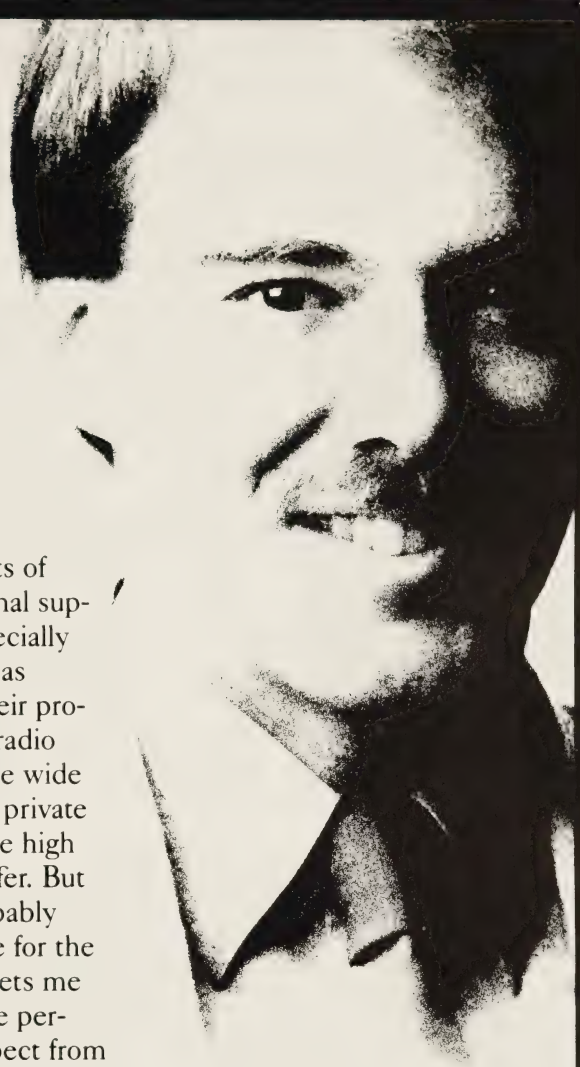
*Editors Note:* If you are interested in the genesis or outcome of any of these resolutions, please contact the Maryland Pharmacists Association offices at (800) 833-7587.

**"Over 3,000  
pharmacies  
belong to  
Valu-Rite.  
There must  
be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."



**SCOTT RICKARDS**  
RICKSAVE DRUG  
NAPLES, MAINE



**McKesson**



# Pharmaceutical Care -- A Consensus Conference

*Ilene H. Zuckerman, Pharm.D., and David G. Miller, P.D.*



*Pharmaceutical care has the potential to bring unity to a profession of diversity.*

The concept of pharmaceutical care, as defined in a model developed by Hepler and Strand, puts forth the pharmacist as the health professional responsible for drug therapy and its outcomes. While many may think pharmaceutical care begins and ends with patient counseling, the actual process is a complex process that includes the pharmacist from the moment that a drug product is selected through monitoring and evaluation of therapeutic outcomes.

Much has been written in the pharmacy literature about the potential of pharmaceutical care to revolutionize our profession. But the implementation of the pharmaceutical care concept -- and its acceptance by pharmacists -- presents a substantial challenge to pharmacy.

Recognizing that fact, the Maryland Pharmacists Association and other Maryland pharmacy organizations hosted a Consensus Conference in October 1992. The purpose of the Conference was to bring together all state practitioner and practice specialty associations, the two local colleges of pharmacy, pharmacy buying groups, and pharmacy boards to discuss the future of Maryland pharmacy and the pharmaceutical care concept.

The Conference consisted of two parts. First, using Dr. Harold Wolf of the University of Utah as a facilitator, the forty-five pharmacist attendees discussed the importance of pharmaceutical care to the future of pharmacy. Then, in an all day session consisting of small and large group workshops, the attendees developed a list of specific issues that need to be resolved before and during the incorporation of the pharmaceutical care model into the daily practice of Maryland pharmacists.

Once these issues were identified, the conference attendees developed a set of goals and measurable objectives for each of the issues. It is these goals and objectives that the organizations attending the conference are now working on together. The complete list of issues, goals and objectives from the Pharmaceutical Care Consensus Conference appears on the next few pages.

The Pharmaceutical Care Consensus Conference had two direct benefits for the pharmacists of Maryland. It represents the first time that all pharmacist and pharmacy organizations and groups joined together to work on a common goal. More importantly, it heralds a long-term work-plan to improve the professional standing of every pharmacist in Maryland. **R**



---

## *Pharmacists must be educated about pharmaceutical care*

---

### **Goal**

Impart information about pharmaceutical care to pharmacy practitioners.

### **Objectives**

- a. Identify Maryland pharmacy's innovators and opinion leaders involved in pharmaceutical care or who are interested in creating pharmaceutical care.
- b. Demonstrate to pharmacists why pharmaceutical care is important and what expectations the consumer and the practitioner should have of pharmaceutical care.
- c. Demonstrate the economic benefits of pharmaceutical care.
- d. Identify funding for demonstration projects to accomplish objectives b and c.
- e. Package and report the results of demonstration projects to consumers, pharmacists, and third-party payers to prove the value of pharmaceutical care.
- f. Develop a step-wise process to enable practitioners to examine and evaluate their own practices areas and how to effect change within those practices.
- g. Refine, unbundle and expand the pharmaceutical care definition and model to make it more acceptable or palatable to practitioners.
- h. Communicate to practitioners that pharmaceutical care is doable within their practice.

### **Consensus Conference Organization Participants**

Maryland Pharmacists Association  
Maryland Society of Hospital Pharmacists  
Maryland Pharmaceutical Society  
Maryland Board of Pharmacy  
District of Columbia Board of Pharmacy  
Chesapeake College of Clinical Pharmacy  
University of Maryland School of Pharmacy  
Howard University College of Pharmacy  
Care Drug Centers  
Maryland Professional Pharmacies/EPIC  
Maryland Association of Chain Drug Stores  
ASCP - Maryland Chapter

### **Goal**

Create and justify an expectation for pharmaceutical care as part of the health care delivery system.

### **Objectives**

- a. Take advantage of technology that is available (eg. guided documentation systems software, modems for exchange of medical information, documentation of patient outcomes and resultant cost savings).
- b. Create a coalition of all the pharmacy organizations in Maryland which would meet on a regular basis to accomplish the following:
  1. Establish a patient's bill of rights and promote.
  2. Take part in developing group methodologies for resources.
  3. Act as a liaison with non-pharmacy groups (third-party payers, employer groups, etc., etc.) to reach out to all customers of pharmacy.
  4. Liaison with other states with common interests in implementing pharmaceutical care.
  5. Develop and disseminate position papers and proofs of pharmaceutical care.
  6. Interact with the legislature about pharmaceutical care.
  7. Develop pilot programs and funding for those programs that demonstrate value for pharmaceutical care.
  8. Identify positive models and resources used by those models and share them with other practitioners.
  9. Develop acceptable outcome measures for pharmaceutical care.
  10. Create continuity within pharmacy.

### **Goal**

Define the roles of each group and interacting roles in effecting change in practice habits in pharmaceutical care.

### **Objectives**

- a. Develop a promotional and marketing strategy for pharmaceutical care.
- b. Identify who are the customers for pharmaceutical care.
- c. Begin educating consumers about the health problems from drug misuse.
- d. Improve pharmacists access to information
- e. Disseminate information through organizations about pharmaceutical care.
- f. Develop a strategic plan for change through legislation/regulation by organizations to implement pharmaceutical care.
- g. Establish a flow of information between practitioner and academicians by using the associations as facilitators.



Stanton Ades (MACDS), Ralph Quarles (MPS), and Melvin Chalet (Care Drug) develop implementation objectives for pharmaceutical care.

---

***Pharmacists don't know how to implement the pharmaceutical care concept in their everyday practice***

---

**Goal**

Enable practitioners to take advantage of existing opportunities to provide pharmaceutical care.

**Objectives**

- a. As an initial effort to implement pharmaceutical care, create and/or determine methods for identifying patients who require or would benefit from pharmaceutical care.
- b. Identify solutions to barriers (eg. making appointments for patients as opposed to waiting for them to come and visit).
- c. Develop relationships with other health care professionals and practitioner groups to solicit referrals and support for pharmaceutical care.
- d. Develop methods to convince third-parties of the value of pharmaceutical care.
- e. Create demand for pharmaceutical care by educating the public to recognize the need for that care and pharmacists' value in providing that care.
- f. Develop political relationships with power brokers so that they are aware of pharmacy's strategic plan of pharmaceutical care.
- g. Create a network of pharmacists who would be able to counter detail physicians with non-biased information about new drugs. This would improve the pharmacist's visibility and reputation amongst the medical community.

**Goal**

Provide pharmacists with resources for providing pharmaceutical care.

**Objectives**

- a. Improve communication by encouraging electronic conferencing and/or bulletin boards.
- b. Create practitioner forums that are non-organizationally based.
- c. Create a distribution method for sharing information about what each organization is doing with other pharmacists (newsletter, journals, etc.)
- d. Improve the transition of patients (continuity of care) through lists of care providers who specialize in various practice areas (diabetes, etc.).
- e. Develop and invest in a public service announcement to be broadcast on a regular basis about pharmaceutical care.
- f. Sponsor, through organizations, a patient drug information line and resource center for pharmacists to use in providing pharmaceutical care.
- g. Publish proceedings of this meeting to participants and others to facilitate discussions and idea flow.

---

***What is the role of supportive personnel and pharmacists in the drug distribution process***

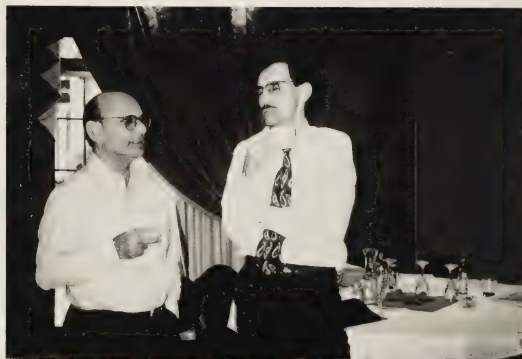
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**Goal**

Have pharmacy technicians assist the pharmacist in non-pharmacotherapeutic functions of the practice.

**Objectives**

- a. Develop and implement a structured training and certification based on a set of standards for Maryland to empower pharmacy technicians to take over some of the functions currently being done by pharmacists.



Melvin Rubin (MD Board) and Richard Pollhammer (MSHP) take a break between work group sessions.



- b. Provide continuous on-the-job training of technicians that is individualized certification or retraining based on practice site and practice needs determined by pharmacists.
- c. Ensure that the pharmacist remains ultimately responsible and accountable for drug product distribution.
- d. List appropriate tasks of supportive personnel through a set of standards and/or principles.

#### **Goal**

To use advancing technology to assist pharmacists in the provision of pharmaceutical care.

#### **Goal**

The drug distribution process, supportive personnel, and pharmacy technology shall be under the authority of a pharmacist who is competent in providing pharmaceutical care.

---

### ***Society does not recognize the importance of pharmaceutical care***

---

#### **Goal**

Increase societal awareness of and demand for pharmaceutical care

#### **Objectives**

- a. Educate consumers, other health care professionals, and payers about what pharmaceutical care is.
- b. Educate the consumer, other health care professionals, and payers about the value of pharmaceutical care.
- c. Educate the consumer, other health care professionals, and payers about the need for pharmaceutical care.
- d. Support interdisciplinary awareness and interaction by students and by existing practitioners with other health care professionals in the academic and institutional settings.

---

### ***Pharmacists must receive reimbursement for pharmaceutical care***

---

#### **Goal**

Obtain reimbursement for pharmaceutical care.

#### **Objectives**

- a. Identify measures to evaluate economic impact of pharmaceutical care (outcomes)
- b. Evaluate economic impact.
- c. Demonstrate non-monetary value from pharmaceutical care.
- d. Foster a productive dialogue with benefit managers about pharmaceutical care.

- e. Identify alternative methods for reimbursement over and above the traditional dispensing fee and cost based reimbursement.
- f. Define units of work other than how many Rx are filled within a specific time period.
- g. Identify direct and indirect methods of reimbursement.
- h. Identify and document interventions through a systematic method including the development of an accounts receivable system that will enable pharmacists to bill for their services.

---

### ***Should pharmacists retain the authority and responsibility for drug distribution for both prescriptions and over the counter medications.***

---

#### **Goal**

Ensure that the use of medications are not compromised. Accept authority for prescription drug use by patients.

#### **Objectives**

- a. Teach versus "train" technicians

---

### ***How do we charge for a service that has traditionally been given away for free?***

---

#### **Goal**

Recognition that pharmaceutical care has a monetary value.

#### **Objectives**

- a. Provide a coupon for a "brown bag" review that would be free for patients. Coupon would say "This service normally has a value/price of this for \$50." This generates a perceived value for the service.

---

### ***Pharmacy needs to create an awareness of pharmaceutical care among other health care professionals.***

---

#### **Goal**

Create an awareness of pharmaceutical care among non-pharmacy health care professionals.

#### **Objectives**

- a. Define and refine concept of pharmaceutical care.
- b. Demonstrate need and benefits to physicians, nurse practitioners, nurse midwives and other health care professionals involved in patient care of pharmaceuticals.

- cal care.
- Provide pharmacy practitioners with the tools to provide information about pharmaceutical care to other health care professionals (especially physicians).
  - Give education in communication.

*Pharmaceutical care will require peer review. That currently does not exist to any great extent within the pharmacy community.*

#### Goal

Increase the willingness of pharmacy practitioners to participate in peer review activities.

#### Objectives

- Define for the pharmacist what peer review is and what its purpose is.
- Lessen the fear and anxiety of peer review activities.
- Show benefits of peer review activities (literature, other professions with peer review).
- Define who is responsible for conducting peer review or establishing peer review groups.

*Are pharmacists competent to provide pharmaceutical care?*

#### Goal

Establish the level of competence needed by pharmacists for pharmaceutical care.

#### Objective

- Identify abilities pharmacists must have to obtain competence (Pharmacists Workup of Drug Therapy).

#### Goal

Assure that pharmacists in Maryland obtain and maintain competence.

#### Objectives

- Develop a system to measure competence (self-assessment, prior learning assessment, tests, peer review, etc.).
- Develop processes that new and existing pharmacists can obtain competence (residency training, care coordinators available to all practice settings, non-traditional Pharm.D. programs, continuing education programs, preceptorships).

R

## PHARMACIST'S LETTER



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# Nuclear Pharmacy Mixup

David B. Brushwood, J.D.



A recent opinion from New York reports on a case that raises several interesting issues. The plaintiff in the case was scheduled to undergo a diagnostic heart scan at the nuclear medicine clinic at the defendant hospital. In preparation for the scan, the plaintiff was to be injected with Thallium-201 Chloride. By error she was injected with Technetium 99m-MDP.

The supervising nuclear pharmacist was preparing standard adult doses of Technetium for patients scheduled for bone scans. When one patient canceled his test after his individual injection had been fully prepared, the pharmacist removed the label, and set the syringe containing the Technetium in a syringe shield to be labeled and used for another scheduled bone scan. A fourth-year pharmacy student had prepared the Thallium injection for the plaintiff and placed the syringe containing the Thallium in a syringe shield while making its label. The shields were less than a foot apart and the pharmacy student erroneously placed the label for plaintiff's injection on the syringe containing Technetium. The error was discovered within minutes after plaintiff had been injected with the Technetium.

The plaintiff commenced a medical malpractice action alleging that the erroneous injection was the cause of bladder pathology that she experienced. The case was dismissed and the plaintiff appealed.

On appeal, one contention of the plaintiff was that the lower court had erred in permitting the introduction into evidence of the hospital record of dose preparation that the pharmacist had made. This record enabled the hospital to show what drug the patient had actually received, and facilitated its proof that the drug could not have caused the patient's injuries. The appellate court held that pharmacist records of this type are admissible as evidence in a lawsuit. This case demonstrates how valuable documentation can be for pharmacists. Without the documentation, the identity of the wrong drug might not have been known, and the allegation that it caused bladder damage might not have been as easy to disprove. R

Based on: *Beck v. Albany Medical Center*, 1993 Westlaw 68140 (N.Y.A.D. March 11, 1993).

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# MPhA Membership Application

Joining MPhA is as simple as checking a few boxes. Just complete this Membership Application and drop it in the mail. It's that easy!

- ☐ Enter my membership in MPhA today but invoice me for my dues.
- ☐ Enter my membership in MPhA today. I am enclosing my \$50 dues for the rest of 1993.

Name \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIPcode \_\_\_\_\_

## Membership Category

Check the box next to your most appropriate membership category:

- ☐ Pharmacy Owner, Manager, or Director  
☐ Staff Pharmacist  
☐ Retired Pharmacist  
☐ Graduate Student  
☐ 1993 Pharmacy Graduate  
☐ 1992 Pharmacy Graduate  
☐ Out-of-State

## Primary Practice Setting

Check the box next to your primary area of pharmacy practice:

- ☐ Community Chain Pharmacy  
☐ Community Independent Pharmacy  
☐ Hospital (Inpatient/Outpatient)  
☐ Long Term Care/Institutional  
☐ Nuclear Pharmacy  
☐ HMO  
☐ Academia  
☐ Government  
☐ Other \_\_\_\_\_

Employer \_\_\_\_\_

Work Phone \_\_\_\_\_

FAX Phone \_\_\_\_\_

## Personal Data

Home Phone \_\_\_\_\_

Legislative District \_\_\_\_\_

Preferred Honorific

☐ P.D. ☐ R.Ph. ☐ Pharm.D.

☐ Other \_\_\_\_\_

## Local Associations

Please check the local organization to which your local association dues portion should be credited.

- |   |  |
|---|--|
| <input type="checkbox"/> Allegany County        | <input type="checkbox"/> Garrett County    |
| <input type="checkbox"/> Anne Arundel County    | <input type="checkbox"/> PG/Montgomery     |
| <input type="checkbox"/> Baltimore Metropolitan | <input type="checkbox"/> Southern Maryland |
| <input type="checkbox"/> Eastern Shore          | <input type="checkbox"/> Upper Bay         |
| <input type="checkbox"/> Frederick County       | <input type="checkbox"/> Washington County |

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To place an ad, send your typewritten copy to MPhA, 650 West Lombard Street, Baltimore, MD 21201-1572. Or you can FAX your ad to (410) 727-2253.

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# *The Maryland Pharmacist*

VOL. 69

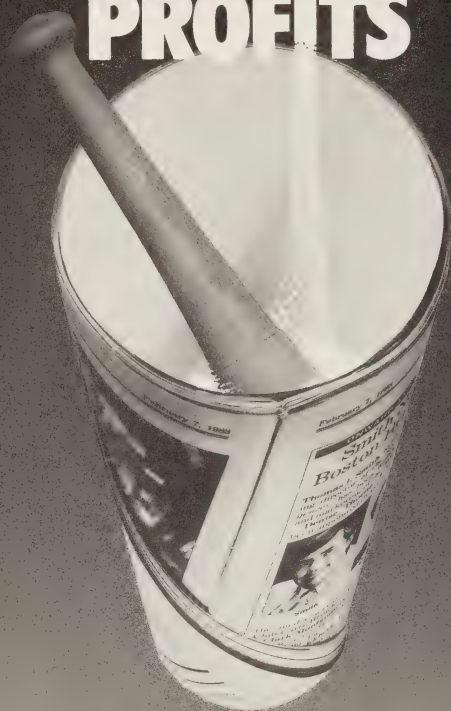
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*MPhA's 1993-1994 President  
Howard R. Schiff*

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# The Maryland Pharmacist

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Number 7

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# President's Commentary

Howard Schiff, P.D.



Recently, I have been asked to think about retirement; that is, not working. What would be my ideal lifestyle when I was no longer in business.

Well, I don't play golf or tennis. I'm not going to watch television all day. I don't have any real hobbies and I can't afford to buy a hotel like Dr. Lenny Berger who owns the Sheraton Ocean City Hotel where we hold our annual convention. What I enjoy doing is what I'm doing right now. Being a pharmacist, counseling patients, and trying to provide pharmaceutical care in my own small part of the profession.

As I take on the responsibilities of the MPhA Presidency, I think about the others out there who feel the same way I do about retirement. Regardless of the difficulties we now face, most of us would simply not think of doing anything else. Our present difficulties are summed up in the four words I frequently hear: "no longer in business."

As State Senator Larry Young said during the Health Care Reform continuing education program at MPhA's convention, independent pharmacists like me may well be "the last of the dinosaurs." Hopefully, when the time comes, I'll be able to sell my pharmacy. Right now, I don't know if it will be viable or, if it is, whether I'll be able to find a buyer.

Economically, all community pharmacies -- independent and chain -- have their problems. Third party payors have become the norm and we have borne the brunt of cost-containment measures. Insurance companies and HMOs have learned how competitive our profession is and how we battle for market share. They miss no opportunity to set one of us against the other while they enjoy the legal protection of the anti-trust laws. Many pharmacists feel that the situation we find ourselves in and what happens to us is far beyond our control. We feel helpless against bigger and more powerful forces.

Well, not quite.

The battle against discriminatory pricing is in its infancy but well on its way. In the past two legislative sessions, we have fought for patients' freedom of choice with some measure of success. We support the efforts of national pharmacy organizations seeking an end to the anti-trust exemptions of insurance companies.

Health care is on the verge of becoming a right of citizenship. Undoubtedly, health care reform will increase the number of prescriptions and the need for pharmaceutical care because the government has already recognized our knowledge and ability to affect therapy outcomes. These changes may give us the opportunity we need to survive and prosper.

In the coming months and years, we will face both the same and greater challenges. What we must continue to do is practice our profession on a one-to-one basis. We must demonstrate that we are the most accessible health care professionals to patients and payors alike. We must continue to fulfill our role as both the front line protector and the last check in the health care system.

# An Inside Look at the Profession

## Results of Schering Report XV

Jack Robbins, Ph.D., Director, Pharmacy Affairs, Schering Laboratories



Although nine out of 10 pharmacists are happy with their choice of pharmacy as a career, increased control by third-party providers and growth in mail-order prescription fulfillment have made some apprehensive about the future of the profession.

These were among the findings of a new, independent survey commissioned by Schering Laboratories.

Schering Report XV, *Is There Life After Pharmacy School? An Inside Look at the Practice of Pharmacy*, focuses on how well satisfied pharmacists are with their choice of pharmacy as a profession, their level of job satisfaction and how their duties shape their feelings -- either negatively or positively -- about their profession. The report also explores steps the pharmacists can take to improve their job satisfaction. The study is based on interviews with 400 pharmacists in independent, chain, supermarket, mass merchandiser and department store pharmacies, as well as in hospitals and HMOs.

### Are You Happy with Pharmacy?

Asked to describe their overall satisfaction with the choice of pharmacy as a career, 51 percent of the pharmacists replied "completely satisfied" and 40 percent "somewhat satisfied." Nine out of 10 pharmacists were happy with their career choice, with only one pharmacist in 10 totally dissatisfied.

The highest level of complete satisfaction (55 percent) was found among pharmacists working in chain and independent pharmacies. In

supermarkets and department stores, the satisfaction levels were 46 percent and 35 percent, respectively. Among pharmacists working in department stores and mass merchandise outlets, a significant 16 percent voiced dissatisfaction with their profession.

Although no differences with respect to job satisfaction were apparent among pharmacy owners, managers or employees, gender did prove to be a factor. Fifty-seven percent of women but only 47 percent of men indicated complete satisfaction with pharmacy as a career choice.

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***Pharmacists need to be assured that they are an integral part of the health care team, not just employees***

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The most frequently cited areas of dissatisfaction were third-party involvement (33 percent), customer relations (28 percent), working conditions (24 percent) and routine clerical work (13 percent).

Involvement by third-party providers was mentioned three times as often by pharmacists working in independent (53 percent) compared to pharmacists in chain pharmacies (18 percent). Not surprisingly, pharmacy owners and managers (40 percent) were more unhappy about dealing with third-party programs than their pharmacy employees (24 percent).

While customer relations was identified as a significant problem by

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**"Talk About Prescriptions" Month &  
National Pharmacy Week  
October 24-30, 1993**



## *Let's Talk*

**S**how your community the value of pharmaceutical care during National Pharmacy Week and "Talk About Prescriptions" Month. The American Pharmaceutical Association (APhA) offers materials for pharmacy week and the National Council on Patient Information and Education (NCPIE) has materials for the month promotion. Order special pro-

motional kits from both organizations—it's never too early to start planning.

For your National Pharmacy Week kit, send a \$5 check payable to Trexco, APhA's promotions company, 1251 Gordon Park Road, Augusta, GA 30901. For more information about the promotional kit and other available products, call APhA's Pub-

lic Relations Department at 1-800-237-APhA. Some products can be specialized for your pharmacy but require 30 days notice.

Order your "Talk About Prescriptions" Month kit by sending an \$8 check to "Talk About Prescriptions" Month kit, NCPIE, 666 11th St., NW, Suite 810, Washington, DC 20001.



36 percent of chain store pharmacists, only 19 percent of independent store pharmacists agreed. Women pharmacists voiced more concerns in this area than men (35 percent versus 25 percent). Among the major complaints -- consumers are often "to grouch" with the pharmacist, especially about prescription prices.

Most dissatisfied about working conditions were pharmacists in department stores/mass merchandisers (46 percent) and supermarkets (39 percent). Among their primary complaints were long working hours and too-short or nonexistent breaks.

Showing the highest dissatisfaction with routine clerical tasks were hospital pharmacists; 25 percent complained about "being bogged down in paperwork."

The Schering Report revealed that fully half of the pharmacists interviewed expressed apprehension about the continuing growth of third-party control of pharmacy. Pharmacists (some 18 percent) also acknowledged the growth of mail-order prescription fulfillment as a probable source of future frustration.

### Does Practice = Satisfaction?

Where pharmacists practiced their profession also emerged as a factor in pharmacist satisfaction levels. Asked to specify the type of pharmacy where they would choose to work if they were just starting out -- but armed with their current knowledge -- the majority of pharmacists said they would repeat their initial choice. Hospital pharmacists were the most satisfied with their first choice of pharmacy (79 percent), followed by pharmacists in independent pharmacies (70 percent), HMO pharmacists (61 percent) and chain-store pharmacists (59 percent).

But among pharmacists in supermarkets, only 36 percent would repeat their choice. For pharmacists in department stores/mass merchandisers, loyalty is a slim 32 percent.

Pharmacists valued each type of pharmacy for its own unique charac-

teristics.

The independent pharmacy was most admired for working conditions (55 percent), especially "more freedom," followed by customer contact (30 percent). Only a handful (8 percent) mentioned benefits, incentives, and salary, or professionalism (also 8 percent).

By contrast, the main attraction of chain-store employment was benefits, incentives, and salary (48 percent). This was followed by customer contact (24 percent) and working conditions (21 percent).

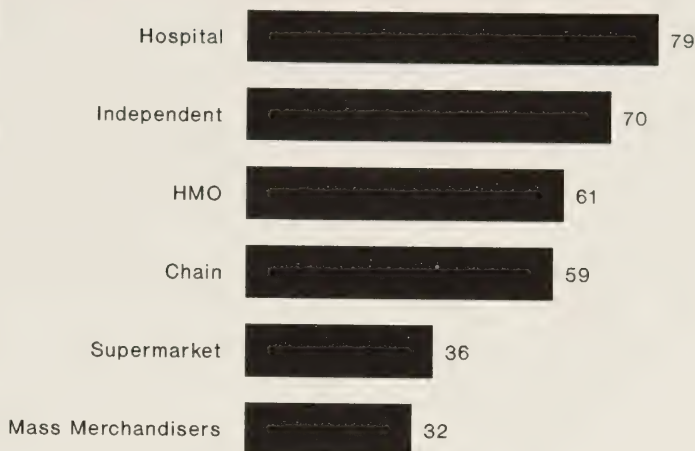
Hospital pharmacies got high marks for both professionalism (33 percent) and working conditions (25 percent).

There was, however, no clear cut pattern concerning a new career choice. About half mentioned "something" in the medical area, including a few who would opt to become dentists, podiatrists or veterinarians. Others would seek a completely new profession, like law.

Interestingly enough, at independent pharmacies, 55 percent of the pharmacists wanted to remain in pharmacy, contrasted with only 36 percent of pharmacy owners.

## Are You Happy With Your Practice Choice?

Percent of Pharmacists Responding "Yes"



### What Would You Rather Do?

The Schering Report also asked pharmacists to list activities on which they would like to spend more time or less time. Given a choice, they would spend more time counseling patients on prescriptions (66 percent), reading professional journals (54 percent) providing advice to customers about non-drug products (47 percent), having discussions with physicians (37 percent), attending pharmaceutical association meetings (37 percent) and addressing non-medical groups like PTAs and social clubs (27 percent).

In effect, many of the duties on which pharmacists want to spend less time involve the sometimes tedious but usually necessary tasks that keep a pharmacy going.

The study noted that a pharmacist's job satisfaction is colored by two factors that shape everyday performance. These are (1) accuracy on the part of superiors in defining what is expected on the job, and (2) performing up to those expectations. Accordingly, the Schering Report asked employee pharmacists to define

the qualities that they believe their supervisors valued most. Their answers fell about equally into two areas: personal qualities (77 percent) and professional qualities (76 percent).

Supervisors and employees perceptions differed when the two groups were asked to rank the importance of the components within the same "quality" categories. For example, in "professional qualities," employees said being customer-oriented was first in importance (39 percent), followed by competence (29 percent) and knowledge (24 percent). Supervisors placed slightly more emphasis (4 percent) on being customer-oriented and slightly less on competence, perhaps taking that trait for granted.

Employees thought promptness (27 percent) was the way to win a supervisor's approval, followed by honesty (23 percent) and pleasant personality (also 23 percent). To the supervisor, however, the number one characteristic was honesty (30 percent). Independent owners, in fact, thought honesty was even more important (45 percent). Among supervisors in general, promptness (25 percent) and pleasant personality (19 percent) were other admirable traits of the ideal pharmacist.

Overall, the images of the ideal employee pharmacist held by pharmacists and their supervisors aren't too far apart. But those who aim to please might put some more stress on their dedication to customers and to demonstrating their job honesty.

**Technicians**

On another subject -- the advent of pharmacy technicians -- 76 percent of the pharmacists reported that their operations employ technicians in addition to pharmacists. Technicians were most common in hospitals (92 percent), and less common in independents (70 percent) and supermarkets (62 percent). Technicians show up most often at pharmacies employing three or more pharmacists (80 percent), and in operations where

each pharmacist must fill 75 or more prescriptions a day (84 percent).

By and large, pharmacists favored the use of technicians. Almost 75 percent said that technicians help pharmacists by filling prescriptions and doing routine tasks, thereby freeing them to perform the professional duties they have been trained to do, such as counseling patients.

Close to 45 percent of the pharmacists said that technicians perform clerical duties such as answering the telephone, serving as cashiers, handling paperwork and records, typing and working the computer, stocking shelves and working with third-party forms.

By an overwhelming 97 percent, pharmacists agreed that technicians make their work easier. In fact, among pharmacists who currently work with technicians, the endorsement level was 99 percent, compared to 90 percent for those with no direct experience with technicians. Only 7

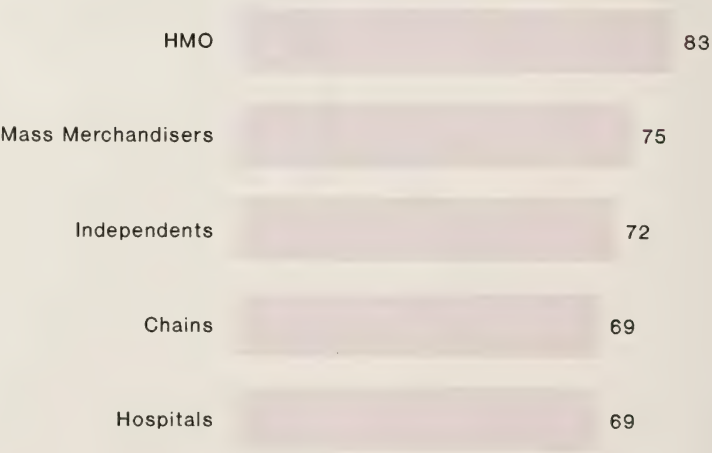
percent felt that technicians pose any kind of threat to pharmacists, and this sentiment came from pharmacists who do not presently work with technicians.

**Burnout**

The Schering Report also addressed job dissatisfaction, especially job burnout, which three out of four pharmacists identified as a problem. Some pharmacists view burnout as a greater problem than do others: 77 percent of women, but only 70 percent of men; 83 percent in HMOs; 75 percent in department stores and supermarkets; 72 percent in independents; and 69 percent in chains and hospitals. In independent pharmacies, 80 percent of owner/managers expressed concern about burnout, compared to 63 percent of their employees.

Can anything be done to help pharmacists avoid burnout? Pharma

**Is "Burnout" A Problem?**  
Percent of Pharmacists Responding "Yes"





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Phone Number \_\_\_\_\_

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cists interviewed in the study offered suggestions in three main areas:

- **Scheduling:** Better hours, more breaks, more convenient shifts (38 percent).
- **Pharmacy technicians:** Hire more "techs" to lighten the workload (28 percent).
- **Knowledge/education:** give pharmacists greater learning opportunities; encourage them to use what they have already learned to better advantage (15 percent).

## What's In Store?

Looking to the future, about 62 percent of the pharmacists foresaw some negative changes immediately ahead in the pharmacy profession. Men (66 percent) were more pessimistic than their female counterparts (55 percent). Expectations were gloomiest at independents, where 84 percent of manager/owners and 71 percent of pharmacist employees saw roadblocks ahead. In contrast, only

44 percent of HMO and an equal number of hospital pharmacists noted some negatives.

On the positive side, 57 percent of the pharmacists expected one or more favorable developments in pharmacy over the next few years. They forecast positive changes in these areas:

- **Patient counseling** (53 percent). More, even mandatory, counseling is expected because of OBRA '90
- **Better education** (12 percent)
- **Control of health-care costs** (10 percent).
- **More computerized operations** (9 percent).

Pharmacist who expressed satisfaction with their choice of profession showed above-average optimism (65 percent). In this category, women (63 percent) were more optimistic about the next few years than men (53 percent).

When pharmacists were asked how satisfied or dissatisfied they were with nine major aspects of their professional lives, there was a significant

degree of dissatisfaction in only one area -- insufficient time to keep up with new developments in pharmacy. Over one in three (37 percent) pharmacists expressed dissatisfaction on this point.

## What Would You Change?

Of course, not every pharmacist was completely satisfied with the other eight aspects of the profession. Pharmacists who expressed complete satisfaction ranked them in this order:

- **Relationship with co-workers** (72 percent) and HMOs (78 percent). Managers (76 percent) felt they were getting along with their co-workers better than employees did (67 percent).
- **Status and prestige as a pharmacist** (45 percent). Pharmacists with more than 15 years experience were more likely to be completely satisfied with their status than pharmacists with fewer years on the job (54 percent versus 37



percent).

- Involvement in administrative decisions (35 percent). Employee pharmacists (20 percent) felt mostly left out here, compared to pharmacy owners and managers (50 percent).
- A role in suggesting staff changes (33 percent). Here again, employees (20 percent) felt they were largely "out in the cold," while 45 percent of owners and managers felt completely satisfied.
- Current salary (30 percent). Pharmacists working in department stores (36 percent) and HMOs (39 percent) were almost as content on the salary issue as pharmacists in independents (40 percent). But there was obvious frustration about paychecks at supermarkets (20 percent) and hospitals (19 percent).
- Policy decisions by management (28 percent). The level of satisfaction was twice as high at independents (46 percent) than at chains (22 percent). Pharmacists in department stores said they were rarely involved in policy decisions that affected them (12 percent).
- Opportunities for promotion (27 percent). Pharmacists in hospitals felt most "boxed in" (15 percent).
- Scheduled salary increases (21 percent). Pharmacists in HMOs (35 percent) were the most pleased with their salary schedules. Pharmacists' replies indicated that salaries increase faster at suburban pharmacies (26 percent) than at urban pharmacies (16 percent).

Pharmacists need to be reassured that they are an integral part of the health care team, not just employees. For many patients, they are the most accessible source of information on medications.

This is an exciting time to be in the profession, with pharmacists enjoying a high degree of prestige among the general public. The task now is to do what is necessary to increase the pharmacist's own satisfaction on the job and with the profession. **R**

## On the Corner

Frank McGinity, P.D.

According to Maryland law, prescribers must write prescriptions legibly and must have an identifiable signature. I thought you'd enjoy deciphering this prescription I recently received. Plus, I've included a few samples sent in by MPhA members. Answers will be revealed next month.

While you're figuring these out, send or FAX your unusual prescriptions to "On the Corner," MPhA, 650 West Lombard Street, Baltimore, Maryland 21201, FAX (410) 727-2253.

*Larotid 200*  
*+ 1 14*  
*i Bud*

From Victor Goodman, P.D.

*Vivichyl 10mg*  
*Tak T + d #20*  
*Refill = #100 @ n n n n n*

From Kathryn Parker, P.D.

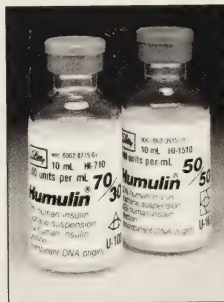
*" 16/10/11 500 mg 9 in*  
*107 R clear*




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# Annual Report of the Board of Pharmacy

*Ralph Small, P.D., Secretary, Maryland State Board of Pharmacy*

*Roslyn Scheer, M.A.S., Executive Director, Maryland State Board of Pharmacy*



In compliance with the provisions as set forth in the Health Occupations Article § 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Nelson J. Sabatini and to the Maryland Pharmacists Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1992 to April 30, 1993. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

## Meetings

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists.

## Officers, Members and Staff

The Board consists of the following officers and commissioners: Steven S. Cohen, President; Ralph Small, Secretary; William E. Adams, Robert J. Kabik, Dorothy Levi, Theodore S. Litwin, Melvin N. Rubin, and George Voxakis. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

The staff consists of Roslyn Sch-

eer, Executive Director; Catherine Putz, Pharmacists Compliance Officer; Tamarra Banks, Computer Officer; Lisa Gray, Secretary; David Oliver, Secretary; Shawnette Fleet, Typist Clerk IV, and Doris Thomas; Renewal/Continuing Education Clerk.

## Examination

The Board conducted examinations for licensure of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 23, 24 and 25 1992 and September 22 and 23, 1992.

The applicants who were examined in June of 1992 were licensed in July, 1992 which is in FY 1993. There were 141 applicants for the Board in June 1992. One hundred thirty-one passed both the theoretical and practical portions of the examination and were licensed. Ten failed the examination.

There were 24 applicants for the Board in September, 1992 (FY 1993). Fourteen passed both the theoretical and practical portions of the examination and were licensed. Ten failed the examination. Data relative to the June 1993 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting of the following: Part I - NABPLEX; Part II consist of: Laboratory, Maryland Drug Law, Federal Drug Law. The NABPLEX and the Federal Drug Exam are obtained from the National Association of Boards of Pharmacy. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The





Year	MD Licenses	Reciprocities	Certifications
1983-1984	92	119	58
1984-1985	92	148	54
1985-1986	109	191	70
1986-1987	105	206	75
1987-1988	121	197	57
1988-1989	135	228	86
1989-1990	167	187	103
1990-1991	156	212	98
1991-1992	149	178	86
1992-1993	145	192	119

Laboratory Examination requires the compounding of four prescriptions per applicant.

The table also shows the number of pharmacists who were licensed by examination during the past ten years.

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers who have stores in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years. The table shows Maryland gained 1,040 pharmacists by reciprocity during the past ten years.

#### Pharmacy Permits

New permits to operate a pharmacy

were issued to 163 firms as of April 30, 1993. These were in the following counties: Allegheny (3), Anne Arundel (2), Baltimore (31), Howard (5), Montgomery (7), Prince Georges (10), Worcester (2), Baltimore City (55).

Of the 115 locations that were issued permits, 11 were name changes. New permits were issued reflecting the changes.

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1993, the Board issued 37 new pharmacy waiver permits as follows: four in Allegheny County, nine in Baltimore County, two Calvert County, four in Carroll County, four in Harford County, four in Howard County, one in Montgomery County, three in Prince Georges County, one in St. Mary's County, two in Talbot County, one in Washington County, and two in Wicomico County.

#### Manufacturers Permits

New permits to manufacture drugs, medicines, toilet articles, dentrifices, or cosmetics as of April 30, 1993 were issued to nine firms.

#### Drug Distributor Permits

The Board issued 155 new permits to distribute prescription drugs as of April 30, 1993.

#### Total Licenses and Permits

The total number of establishments licensed through the State of Maryland is 1,387 and the total number of pharmacists is 5,756 as of April 30, 1993.

#### Legislation

The following bills which affect pharmacy either directly or indirectly were enacted by the 1993 General Assembly. These bills must be signed by the Governor to become effective.

SB 513 - CRNP/Authority to Dispense - Allows nurse practitioners to dispense.

SB 104 - Maryland State Board of Pharmacy - Altered the requirement that two-thirds of members of the State Board of Pharmacy vote in favor of a disciplinary action. The requirement is now a majority vote.

### Cooperative Activities

The Board maintained cooperative activities with the Division of Drug Control, Licensing and Certification, the State Department of Health and Mental Hygiene, the University of Maryland - School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Consultant Pharmacists, City, County and State Police, the National Association of Boards of Pharmacy, and all Pharmacy Boards and Schools throughout the country.

### Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts and other state boards of pharmacy. The wide range of complaints varied in severity. Listed in the table are statistics concerning the types of complaints for the period of May 1992 through April 1993.

During the period of FY 1993, ten orders were issued and distributed for public information and two CE Requirement Orders were not distributed or public information. These 12 Orders all involved pharmacists, which included: emergency suspensions (1), suspensions with immediate stay and probation (5), revocation of license (1), full reinstatement (3), surrender (2), reprimand (1), CE Requirements (2).

During this period, the Board voted charges for violation of pharmacy law against 25 pharmacists. Fifteen pharmacist cases have been concluded (included in the above statistics) and

<i>Complaints Filed with the Maryland Board of Pharmacy</i>	
Miscellaneous*	9
Mislabeled Prescriptions	5
Incorrect Drug Dispensed	21
Shortages of Controlled Drugs	1
Communication	1
Dispensing Habits of Pharmacist	5
Fraud	1
Professionally, Physically or Mentally Incompetent	1
Pricing	1
Freedom of Choice	1
Rx not Dispensed	2
Advertisement	5
Theft of Drugs	2
Sexual Misconduct	1
Impaired/Chemical Dependency	2
Failure to Protect Patient Confidentiality	8
Board Action by Another State	6
<b>Total Complaints</b>	<b>72</b>
* Complaints are on expired prescriptions, failure to protect patient confidentiality, and generic substitution.	

ten are outstanding. Of these, one pharmacist's license is currently suspended on an emergency basis pending final resolution. The Board has 19 additional outstanding cases from the previous year which have not been concluded.

Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations according to the section of 12 - 313(b) of the Health Occupations Article and the number of pharmacists convicted of each: (4) Provides professional services while (i) Under the influence of alcohol; or (ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts or without valid medical indication (3 convictions); (7) Willfully fails to file or record any report that is required by law (1 conviction); (14) Without first having received a written or oral prescription for the drug from an authorized prescriber, dispensed any

drug for which a prescription is required (3 convictions); (15) Except as provided in §12-511 of this title, unless an authorized prescriber authorizes the refill in the original prescription or by oral order, refills a prescription for any drug for which a prescription is required (1 conviction); (16) Violates any provision of §12-603 of this title, which concerns the labeling requirements for prescription medicines (2 convictions); (20) Is professionally, physically, or mentally incompetent (3 convictions); (21) Is convicted of or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside (1 conviction).

### Data Processing

The Board is in the process of completing its Office Automation Plan based on guidelines by the Department of Health and Mental

Hygiene. Once this plan is completed, the Board expects to provide more efficient and effective data management services.

### Finances

Beginning July 1, 1993, the Board of Pharmacy pays all funds collected to the Comptroller of the State who distributes the fees to the State Board of Pharmacy Fund. Disbursements covering the expenses of the Board are paid by voucher by the State Comptroller from the State Board of Pharmacy Fund. This is the first year that the Board's revenues must completely fund all Board expenditures. The Board may not receive any other State funds.

### Financial Statement

The Board of Pharmacy had revenues of \$245,735 in 1991 and \$257,272 in 1992. The Board of Pharmacy had expenditures of \$165,624 in 1991. The Board's direct budget for 1992 was \$160,154 with indirect costs of \$205,095. For 1993, the Board's budget is \$560,744. This includes all costs. In the past many of these costs were not assigned to the Board and funded by the Department of Health and Mental Hygiene.

### Regulations

The Board promulgated the following regulations, either amended or new: 10.34.07 - Pharmacy Equipment (amended); 10.34.09 - Fees (amended); 10.34.19 - Parenteral/Sterile Enteral Compounding (amended); 10.34.22 - Licensing of Wholesale Prescription Drug (new). The Board has the following regulations in progress: 10.34.03 - Acute Care Regulations (new); 10.34.23 - Long Term Care Facilities (new). During 1993, as required by law, the Board is reviewing all of its regulations in the Regulatory Review Process. The results of that review will be reported in the next Annual Report.

### Continuing Education

Throughout the year, the Continuing Education Task Force has accepted requests for approval of Continuing Education (CE) programs that are not automatically approved by the CE regulations. The third monitoring of CE documentation was completed with all pharmacists in compliance with the requirements.

A CE recording sheet has been developed to be included with license renewal applications so that each pharmacist will return a list of at least 30 earned CE hours with his/her renewal form. This sheet will be included with the 1993 renewal application and each year thereafter.

### Secretary-Treasurer's Message

The Maryland State Board of Pharmacy is a State Health Regulatory Board established by the legislature for the purpose of regulating the practice of pharmacy and the manufacture, distribution, sale and storage of prescription drugs; and for the purpose of protecting the health, safety, and welfare of the citizens of Maryland. The Board regulates pharmacists as well as pharmacies. In order to fulfill its responsibilities required by law, the Board licenses pharmacists and issues a permit to pharmacies, drug manufacturers, and distributors, investigates complaints, monitors inspection reports derived from the Division of Drug Control, and disciplines violators of the laws regarding the practice of pharmacy.

The Board accomplishes its purpose by regulating the practice of pharmacy to ensure that:

1. Acceptable skill levels of those entering the practice of pharmacy are maintained;
2. Acceptable standards of professional practice are followed;
3. Distribution of prescription drugs is controlled;
4. Misuse and diversion of prescription drugs from pharmacies, manufacturers, and distributors are prevented.

5. Controlled substance prescription drugs are properly and legally distributed;

6. Cooperation with other State and federal agencies is achieved.

The Board is a State agency that develops and sets its policy through eight Board members appointed by the Governor. Steven Cohen is again serving as President and I, Ralph Small, have again been elected Secretary. Other pharmacist members of the Board are Robert Kabik, Dorothy Levi, Melvin Rubin, and George Voxakis. The two other members, William Adams and Theodore Litwin, are non-pharmacist public members. The Board employs an Executive Director, Roslyn Scheer, to manage the agency, and to implement the Board's policies and procedures.

Effective July 1, 1992, the Board of Pharmacy became a special fund agency with the creation of the Board of Pharmacy Fund. The revenues in the Board of Pharmacy Fund are to be used exclusively to cover the costs of operating the Board. No other funds may be used to fund Board activities. The Board must be self sustaining. No funds are received from the State's General Fund.

As a result of special funding, the Board developed a plan to hire a full complement of staff. Staffing of the Board, which had fallen to its lowest level since 1979 due to hiring freezes, was compensated for by Board members performing clerical tasks. With the implementation of SB 655, the Board was able to fill the vacant positions that had existed previously and to add a Computer Officer and Pharmacist Compliance Officer.

Methodology in how the Board administers policies and rules has undergone tremendous change in the past year. All the Health Boards and the Commission are working in concert with the Health Department to insure that clear cut objectives are set, and that those objectives are met. The Board has been successful in working within the newly established guidelines to bring about a smooth transition.





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# Osteoporosis

## *Are Your Patients Receiving the Proper Care?*

Peter P. Lamy, Ph.D., Sc.D., University of Maryland School of Pharmacy



Osteoarthritis (OA, degenerative joint disease) is of diverse etiology and obscure pathogenesis. Clinically, it is a disease characterized by joint pain, tenderness, limitation of movement, occasional effusion, and variable degrees of local inflammation, but without systemic effect.<sup>1</sup> It can further be characterized pathologically, histologically, biomechanically, and biochemically. Therapeutically, the disease is characterized by a lack of a specific healing agent. Unfortunately, the nonsteroidal anti-inflammatory agents are often used inappropriately to manage this disease. These drugs heighten the risk of elderly to gastrointestinal and kidney problems.<sup>2</sup>

OA is nearly unknown in children and is rare in young adults. There is a progressive increase with age in the prevalence of severe OA (grades 3 or 4, i.e. those grades most likely to be accompanied by symptoms). Furthermore, after 50 years of age, the relation is probably not linear but exponential.<sup>3</sup> While only about two percent of women less than 45 years old appear to have OA, the prevalence rises to approximately 30 percent of women between 45 and 64 years of age, and to 68 percent for those older than 65. Statistics for men are similar, although somewhat lower in the upper two age groups.<sup>4</sup> Data from post-mortem studies show that 60 percent of people have some degree of articular cartilage degeneration in many joints by the time they are 60 years old.<sup>5</sup> Very little is known about the impact of OA on function and/or quality of life in affected individuals.

Involvement of the shoulder, spine, hip and/or knee may result in loss of motion and inability to perform a host of self care activities. Particular attention ought to be paid to the possible development of and prevention of contractures.

Symptomatic OA is important clinically, since symptomatic persons are more likely to seek care. Fifty-six percent of men and 80 percent of women with radiographic evidence of knee OA reported symptoms.<sup>4</sup> Data from NHANES I indicate that 43 percent of persons with knee OA reported pain.<sup>6</sup> Data from the Framingham study cohort show that 40 percent of persons aged 63 to 94 with radiographic evidence of knee OA report symptoms.<sup>7</sup> NHANES I also reports that 20 percent of persons with moderate radiographic evidence of hip OA reported symptoms, whereas 57 percent of these with prevalence, location, and severity of OA have been identified.<sup>3</sup> Women have a higher prevalence and severity of OA of the body trunk (spine, hip, and disc degeneration of the spine). Women also have greater multiple joint involvement than men.<sup>4</sup>

Prevalence and distribution of joint involvement also vary by geographic location and ethnicity.<sup>8-10</sup> South African studies have compared white and black populations.<sup>11</sup> Osteoarthritis of the hands, feet, and hips as well as multiple involvement (more than three joints) is less prevalent in black than white women. However, more black men have had OA than white men.<sup>11,12</sup> There is low prevalence of hip OA in the black population.<sup>10</sup> Knee OA is more

prevalent in black compared to white South Africans.<sup>11</sup>

### Management of Osteoporosis

#### *Non-pharmacological Approaches*

Perhaps more than 10 percent of community living elderly have trouble leaving their home, and arthritis is the most common condition reported by those age 65 and over as being responsible, exceeding the impact of hypertension, ischemic heart disease, and cerebrovascular disease.<sup>13</sup>

The final pathway of all forms of arthritis is locomotor disability. It is a reliable marker of active, usually inadequately managed disease.<sup>14</sup> Periodic formal assessment, with a rapid response to new decline in independence is central to the non-pharmacologic approach to osteoarthritis. That non-pharmacologic approach revolves around sophisticated use of many assistive devices available, but primary providers of care for the elderly (the formal and informal network of caregivers) may have little or no formal training in interventions and services available to the elderly using these devices.<sup>15,16</sup>

Most important is recognizing and managing the elderly person's ability to function safely at home, a concept that has gained in importance since cost containment measures have forced earlier discharge of patients jeopardizing the barely compensated person's ability to function independently and safely. To assess the elderly's ability to function, the Modified Barthel Index or a simple measure can be used to screen for

functional difficulties. It requires minimal training to administer.<sup>17,18</sup> In addition, health care providers and caregivers will need to become more familiar with the various ambulatory aids, hygiene aids, positioning aids, as well as the other assistive devices that are needed to support the OA patient.

*Pharmacological Approaches* Non-acetylated aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) are among the most often used drugs in the world. The elderly account for a majority of that use. Although these drugs improve the quality of life for many elderly, rational dosing of these drugs and the consequences of their consumption for geriatric patients are not adequately understood. These drugs account for over one-half of all adverse drug reactions from all drugs reported to the Food and Drug Administration. Large gaps exist in our understanding of their pharmacokinetics and pharmacodynamics, particularly in the elderly. In the elderly, adverse effects can be divided into two categories: gastropathy and adverse renal effects.<sup>20</sup> The FDA indicates that there are so many GI bleeds associated with the use of NSAIDs that only 10 percent of them are actually reported.<sup>21</sup>

Gastrointestinal bleeds occur seven times more often in the elderly population than in younger people. Over 10 percent of these bleeds are fatal.<sup>22,23</sup> Both local and systemic effects appear to be involved. Most of the cost of the medical hospitalization seen in arthritis are due to gastropathy of NSAIDs and

they extrapolate to a cost in the multimillion of dollars, not counting the cost to elderly in reduction in their quality of life.<sup>24</sup>

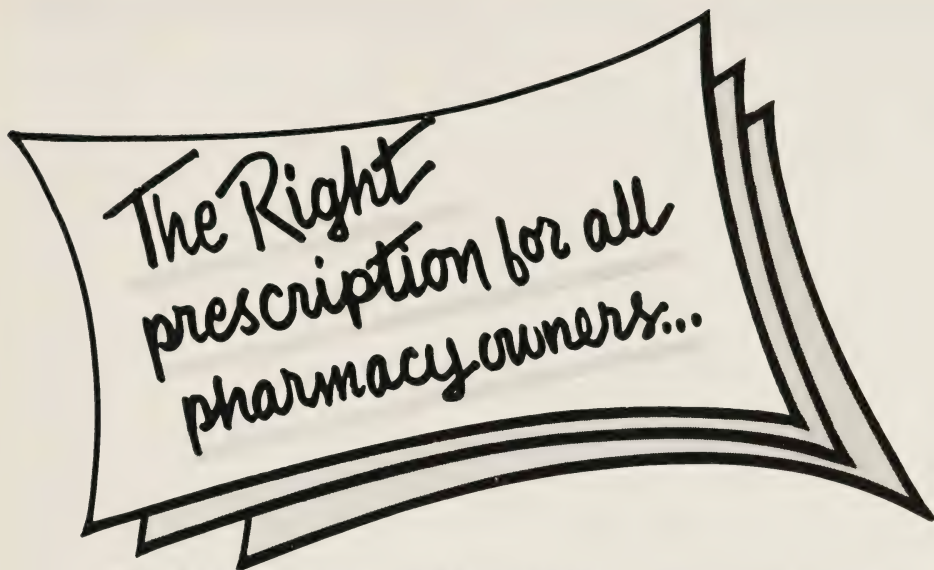
The danger of adverse renal effects when these drugs are used has been described.<sup>25</sup> In a number of clinical conditions, including congestive heart failure, cirrhosis, renal insufficiency and hypovolemia (many elderly receive diuretics and are probably hypovolemic), endogenous prostaglandin is critical to the continued functioning of the kidneys. When patients with these disorders receive NSAIDs (either prescription or non-prescription), they are at risk to an acute ischemic insult to the kidney, because inhibition of prostaglandin allows unopposed vasoconstriction.<sup>26,27</sup>

In the elderly, central nervous system effects have also been reported which manifest as tinnitus or hearing loss and also cognitive dysfunction and even visual disturbances.

Finally, the NSAIDs may be involved in a number of pharmacokinetic and pharmacodynamic interaction, such as with digoxin, antihypertensive medications, and many others.

Ideally, NSAIDs should not be relied upon in nonsystemic musculoskeletal conditions after serious gastropathy. Simple analgesics, appropriate rehabilitative modalities, and support mechanisms for weight-bearing joints, as well as behavioral medicine/pain control modalities would be more desirable.





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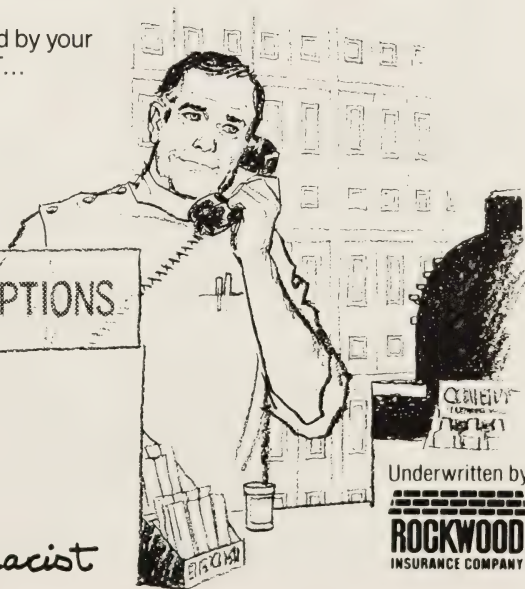
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# Drug Information Questions

## *Helping Patients with Migraine Headaches*

Blanca Morales, Pharm.D., Babette S. Prince, Pharm.D., UMAB Drug Information Center

*This article provided under a grant-in-aid from Glaxo*

### **Drug Information Request**

I have seen a variety of drugs used to prevent migraine headaches. Which are effective and why?

### **Response**

Headache ranks ninth among causes of visits to physicians and is a major source of time lost from work. In addition, it is also the cause for many diagnostic procedures performed today.<sup>1</sup> Migraine is defined as a familial disorder characterized by episodic attacks of headache variable in onset, duration, intensity and frequency.<sup>2</sup> Migraine headaches are described as a throbbing ache, progressing rapidly within a few hours and sometimes lasting days. Commonly, the pain is preceded by GI complaints (nausea, vomiting, anorexia) and/or mood disturbances. A number of risk or trigger factors have been associated with the occurrence of migraine headaches including dietary, environmental, psychological and pharmacologic precipitants.<sup>3,4</sup>

### **Pathophysiology of Migraines**

The etiology and pathophysiology of migraine headaches remain inconclusive. Many biochemical changes have been identified in association with migraine headaches. Various mediators have been implicated, including histamine, prostaglandins, norepinephrine, serotonin, bradykinin and substance P.<sup>2,4</sup> Migraines are considered a disorder of cerebrovascular regulation in which a cascade of events results in a vasoconstrictive followed by a vasodilatory phase. The vasoconstrictive phase is accompanied by a neurologic phase characterized by visual symptoms, unilateral paresthesias, hemiparesis or hemisensory defects. This is followed by a reactive vasodilation which produces the actual pain.<sup>3,4</sup> Migraine headaches are classified as common, classic or complicated, distinguishable by the presence or absence of a neurologic phase. The neurologic phase of the classic migraine has been associated with a decrease in brain blood flow. This has been implicated as one of the possible causes of the neurologic features preceding the

actual headache.<sup>2,5</sup> Common migraine is similar to classic migraine except that the neurologic symptoms are absent. Complicated migraine is a term used to describe migraine attacks in which the focal neurologic defects may last the entire headache attack. It has been postulated that such patients may show areas of ischemic brain infarctions involving the functionally impaired region.<sup>1</sup>

### **Therapeutic Solutions**

Prophylactic therapy should be considered for patients with attacks that disrupt their lives, when attacks recur more than twice a month, and when migraines become refractory to abortive therapy. There are several goals when considering migraine patients. The most important principle in migraine patients is prevention. In patients who experience attacks, the main concerns are to abort the attacks, reduce their frequency and severity, and prevent recurrence. The ideal prophylactic agent should be oral, long-acting, have few and tolerable adverse effects and be effective in preventing migraine attacks.<sup>5-7</sup>

Numerous drugs have been used empirically in an attempt to find the most efficacious agent to prevent recurrence of migraine headaches.

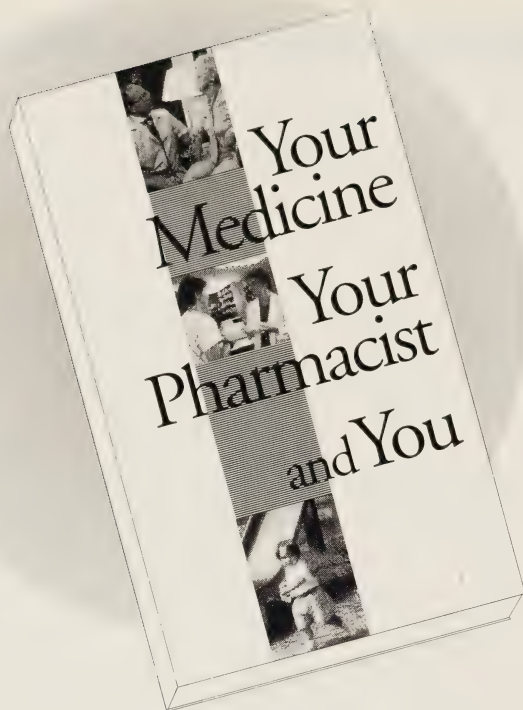
The pharmacologic properties of these agents are diverse, although their effectiveness in controlling migraine headaches is very similar. The efficacy of these agents is linked to their action on vascular smooth muscle and blockage of serotonin (5-HT), adrenergic and prostaglandins pathways.<sup>2,4</sup>

Traditional therapies used for migraine prophylaxis include ergot preparations, beta blockers, tricyclic antidepressants, and calcium channel blockers. In many instances traditional therapy provides satisfactory results; however, in many cases undesirable adverse effects may limit their usefulness.

### **Ergot Derivatives**

Ergot derivatives remain widely used for the prophylaxis of migraine headaches. Methysergide is a semisynthetic ergot alkaloid. It is a competitive peripheral antagonist of





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serotonin (5-HT), but may act as a serotonin agonist in the central nervous system. The efficacy of ergots in migraine prophylaxis results from their effects on humoral factors that alter the pain threshold. These effects include blood vessel permeability, inhibition of histamine release from mast cells, and potentiation of plasmakinin-induced pain resulting from serotonin. Methysergide is a very effective prophylactic agent for vascular headaches, but ineffective in treating acute attacks. The adult prophylactic dose is 4-8 mg in divided doses taken with meals. The drug should not be administered continuously and a drug-free period of 3-4 weeks every 6 months should be provided. The dose should be gradually decreased during the 2-3 week period prior to discontinuation, to prevent rebound headaches.<sup>8</sup> The adverse effect profiles of the ergots have led physicians to look for therapeutic alternatives. Nausea and vomiting are common gastrointestinal adverse effects seen with short term therapy; advising the patient to take the drug with food will minimize these problems. Long term adverse effects such as vascular toxicity (paresthesias), and fibrotic complications (fibrous tissue in lungs and heart) are of major concern, and unpredictable in nature. Although signs and symptoms of toxicity are non-specific, patients should be closely monitored for increased fatigue, weight loss, flank pain, decreased urinary output, chest pain, dyspnea, fever, leg pain and edema. Patients should be reminded to adhere to maximum recommended dosages in order to minimize the potential for adverse effects.<sup>6,8</sup>

### Beta Blockers

In the event ergot toxicity or failure occurs, empiric trials with different types of drugs become necessary. Beta-blockers are commonly employed for migraine prophylaxis. The exact mechanism of action is unknown, but may be related to inhibition of vasodilation or inhibition of arterial spasm.<sup>8</sup> In general, beta-blockers are considered safe and effective drugs in the prophylaxis of migraine headaches. Propranolol has been widely studied and found to be effective in preventing or reducing the number of attacks in 60-80% of patients in doses ranging from 80-240 mg/day.<sup>6,9</sup> Treatment should begin with 20 mg twice a day, followed by gradual increases until satisfactory migraine control is achieved or adverse effects develop. Doses higher than 240 mg/day have not been found to provide additional therapeutic benefit.<sup>9</sup>

A number of other beta-blockers (nadolol, timolol and metoprolol) have been found to be as effective as propranolol for preventing migraine attacks. Adverse effect profiles of these drugs vary according to the specific agent's lipid solubility, intrinsic sympathomimetic activity (ISA) and receptor selectivity.<sup>6,7</sup> Adverse effects such as drowsiness, depression and gastrointestinal complaints are common, and often the reason for drug discontinuation. The use of a more cardioselective or less lipophilic agent

may reduce the incidence of some of these adverse effects. Patients who do not benefit from one particular beta-blocker may obtain significant benefit from another. The combination of beta-blockers and ergot products should be avoided, as it can lead to pronounced peripheral ischemia. Beta-blockers with intrinsic sympathomimetic activity (pindolol and acebutolol) do not appear to have antimigraine activity. Timolol and propranolol are the only two beta-blockers currently labeled for use as migraine prophylaxis agents.<sup>8</sup>

### Tricyclic Antidepressants

The prophylactic effectiveness of tricyclic antidepressants in patients with mixed migraine and tension headaches is well established. The effectiveness of agents such as amitriptyline, doxepin, and nortriptyline compare to that of beta-blockers and ergot products.<sup>6,7</sup> The mechanism of action of these drugs in migraine prophylaxis does not appear to be related to their antidepressant properties, but instead, to a direct blockade of serotonin-2 receptors and norepinephrine reuptake in the brain.<sup>7,8</sup> In a placebo controlled double-blind study of 30 patients with migraine, amitriptyline doses of 50-150 mg were found to be as effective as propranolol at doses of 80-240 mg.<sup>9</sup> The effective dose of amitriptyline ranges from 25-175 mg per day. Therapy should be started at 10 mg, given at bedtime, followed by an upward titration of 10 mg biweekly. Evening single doses are recommended to minimize daytime sedation and adverse effects. Morland *et al* looked at the effectiveness of doxepin 100 mg a day in a double-blind crossover study of 23 patients compared to placebo. Doxepin was as efficacious as amitriptyline for the prevention of migraine headaches.<sup>10</sup>

The most common adverse effects seen with these drugs are related to their anticholinergic properties, and include dry mouth, constipation, urinary retention, blurred vision and orthostasis. Tricyclic antidepressants should be used with caution in patients with cardiac rhythm disturbances, marked renal impairment, benign prostatic hypertrophy, and in the elderly population.<sup>8</sup> These agents provide alternative therapy for patients who have received other prophylactic agents without success, and/or are ingesting large doses of analgesics and ergotamine preparations.

### Calcium Channel Blockers

Much attention has been given to the potential benefits of calcium channel blockers (CCB) as prophylactic agents for migraine headaches. Results obtained from CCB studies are similar to those achieved with standard therapy such as propranolol.<sup>11</sup> CCBs inhibit the entrance of extracellular calcium into cephalic vascular smooth muscle, and block intracerebral vasoconstriction induced by vasoactive neurotransmitters, such as 5-HT and norepinephrine.<sup>12</sup> Of the currently marketed CCBs,

verapamil is the most widely studied. Verapamil exerts vasodilatory action on cerebral arteries and interacts with serotonergic receptors. This action on serotonin receptors may be of more significance in preventing migraine attacks than its vasodilatory actions.<sup>12</sup> In doses of 240-320 mg, verapamil has been effective in 70% of patients, with better results reported at higher doses.<sup>13</sup> The major reported adverse effects with verapamil include constipation, dizziness, fatigue, nausea and abdominal discomfort.<sup>8,14</sup> Nimodipine, a selective CCB for cephalic blood vessels, has also been studied as a prophylactic agent for vascular headaches. Studies using doses of 60-120 mg daily have yielded controversial results. Mechanistically, one would expect nimodipine to have marked beneficial effects in migraine headaches, however, results have only been modest.<sup>15</sup> Due to the limited number of studies available, it is difficult to draw solid conclusions. In addition, optimal dosing of CCBs and their long term efficacy for migraine prophylaxis is not well documented. Preliminary studies show promising results for CCB in the prevention of migraines especially for refractory patients or those experiencing intolerable adverse effects to more conventional therapy.

Flunarizine, an investigational agent, is a non-selective CCB with potent anti-spasmodic action. Flunarizine inhibits calcium influx into vascular smooth muscle cells.<sup>16,17</sup> It is a highly lipophilic agent that is distributed into adipose tissue, and crosses the blood-brain barrier in significant amounts. The drug is metabolized by the liver, and undergoes significant first-pass effect once absorbed from the gastrointestinal tract. Flunarizine is highly protein-bound in plasma and tissue, with an elimination half-life of 7-10 days.<sup>18</sup> There are several postulated mechanisms for flunarizine's actions. Research on the drug's action has established that flunarizine has no myogenic effect on vessels, escaping any vasodilatory and arterial pressure changes that may occur. Flunarizine's ability to protect brain cells from hypoxia has also been demonstrated.<sup>18</sup> Flunarizine has been shown to influence the release of neurotransmitters (such as dopamine), reduce the epileptic-neuronal activity, and, in animal studies, to induce behavioral changes similar to those seen with haloperidol.<sup>19</sup>

Studies of flunarizine's long-term efficacy suggest its effectiveness increases over time. A 12 month multicenter study (six month prophylactic regimen followed by 6 month with no treatment) evaluated the long-term efficacy of flunarizine and its adverse effects. The study enrolled 100 patients diagnosed with migraine. Ten milligrams of flunarizine was administered daily for the first month, then daily for 3 weeks a month. Every 3 months, patients were evaluated for headache related parameters (headache index score, analgesic consumption, number of headache affected days), and for other variables such as anxiety, sleep quality, mood, body weight, and adverse effects. Ninety-two patients completed

Substance	Notes
Caffeine	Coffee, tea, iced tea and cola. Decaffeinated versions are OK.
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Cheese	Excepting cream, cottage, and American cheese. Including pizza and macaroni with cheese.
Yogurt and Sour Cream	
Nuts	Including peanut butter.
Processed Meats	Those that are aged, canned, cured, marinated, tenderized or contain nitrates or nitrites. Including hot dogs, sausage, bacon, salami, and bologna.
Alcoholic Drinks	Especially red wine, champagne, and dark or heavy drinks.
Monosodium Glutamate	Chinese restaurant food, many snack foods and prepared foods, Accent and other seasoning products. <i>Read labels.</i>
Citrus Fruits and Juices	Oranges, grapefruits, lemons, limes, and pineapples and their juices.
Certain Other Fruits	Bananas, raisins, red plums, canned figs and avocados.
Certain Vegetables	Broad, lima, Fava and navy beans; pea pods, sauerkraut, and onions.
Certain Bread Products	Homemade yeast breads, sour-dough breads, and other yeast-risen baked goods.
Decongestants	Pseudoephedrine, phenylpropanolamine, phenylephrine.

### *Substances to Avoid in Migraine Headache Patients<sup>23</sup>*



the first phase. At 6 months, 70.6% of patients (n=65) reported a decrease in headaches of at least 60% ( $p < 0.001$ ). At 12 months, 40.5% of patients (n=32) continued to have benefit from the drug during the following 6 months without therapy. Common adverse effects reported included weight gain (n=30), drowsiness (n=26), weakness (n=8) and depression (n=3). The authors concluded that flunarizine was efficacious in providing migraine prophylaxis even after drug discontinuation. This mode of administration reduced adverse effects without considerable loss in drug efficacy.<sup>20</sup> Once available, flunarizine may provide a therapeutic alternative that can be added to the available agents used in the prophylaxis of migraine headaches. The lag time to maximum concentration of flunarizine may be disadvantageous, since recurring migraine headaches may require continued use of analgesics. Long term safety, efficacy and optimal dosage regimens need to be established. Flunarizine's long duration of action provides the benefit of once daily administration, and may allow for drug free periods. However, more studies are necessary to explore this therapeutic alternative.

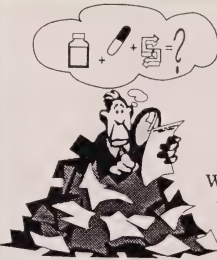
Despite the variety of agents available for migraine prophylaxis, significant numbers of patients still suffer from migraine headaches. Failure to identify the best possible prophylactic agent for a particular patient can cause more frequent use of analgesics, which may in turn introduce other concerns regarding abuse potential and tolerance. When selecting an agent, one should look not only at effectiveness, but also at the adverse effect profiles. With proper diagnosis and intelligent use of prophylactic agents, patients should obtain maximum relief from migraine headaches with minimal alteration of their daily activities. **R**

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# Continuing Education

## Continuing Education Quiz

July 1993 -- Migraine Headaches

This month's questions are taken from the article on migraine headaches that appear in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by January 31, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

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1. Which of the following chemical mediators has not been associated with migraines:
  - a. serotonin
  - b. norepinephrine
  - c. histamine
  - d. acetylcholine
2. The neurologic symptoms of classic and complicated migraine may be tied to:
  - a. decreased brain blood flow
  - b. increased brain blood flow
  - c. minor ischemic attacks in the cerebellum
  - d. minor ischemic attacks in the cerebrum
3. Effective pharmacologic management of migraine headaches has the following primary goal:
  - a. symptomatic relief
  - b. prevention
  - c. compliance
  - d. minimization of side effects
4. Short and long term effects of ergotamines include:
  - a. nausea and vomiting
  - b. anticholinergic effects
  - c. weight loss
  - d. all of the above
5. Studies on the use of beta blockers in the prevention of migraine show:
  - a. minimum effectiveness in patients
  - b. 10 to 20% effectiveness in patients
  - c. 40 to 50% effectiveness in patients
  - d. 60 to 80% effectiveness in patients
6. Combinations of beta-blockers, ergotamines, and antidepressants are more effective than single agents alone:
  - a. true
  - b. false
7. Tricyclic antidepressants' effectiveness in migraines is due to their:
  - a. blocking of norepinephrine reuptake
  - b. blocking of serotonin-2 receptors
  - c. antidepressant effects
  - d. a and b only
8. Migraine patients using CCBs should be warned about:
  - a. constipation, dizziness and GI upset
  - b. visual disturbances, syncope and GI upset
  - c. diarrhea, parasthesias, and UV sensitivity
  - d. constipation, GI upset and visual disturbances
9. Advise your migraine patients to avoid:
  - a. megadoses of vitamins and caffeine
  - b. honey and bee pollen byproducts
  - c. citrus fruits and antihistamines
  - d. caffeine, aged cheeses, and MSG
10. All of the following are true about flunarizine except:
  - a. it is an investigational drug
  - b. it is a selective CCB
  - c. it is hepatically metabolized
  - d. it protects brain cells from hypoxia



# Pharmacist Profits From Invention

David B. Brushwood, J.D.



In June of 1985, a pharmacist contacted a pharmaceutical manufacturer and told the manufacturer about an idea he had for a sterile saline solution for use in inhalation therapy. The president of the company told the pharmacist that the company's sales and marketing staff and board of directors were enthusiastic about the idea. Thereafter, the company developed the product with the pharmacist's frequent input.

From time to time, the pharmacist and the company president discussed the royalty that the company would pay. The pharmacist suggested that the industry standard was 5 percent. On December 9, 1986, the board of directors directed the company president to get a firm agreement with the pharmacist concerning a royalty for the product. The company offered 1.9 percent. The pharmacist counter offered at 3.5 percent, and the president agreed. Royalties were paid until 1989, when they were stopped.

The pharmacist sued the company to recover royalties due. By that time, another person was president of the company, and the company argued that the president of the company who had agreed to pay 3.5 percent had done so without authority. Evidently there were some members of the board who felt that the earlier president had been too generous to the pharmacist. There had also been a desire expressed by the board to have no royalty paid until some minimum level of sales had been met.

The court held that the agreement between the president and the pharmacist was enforceable. The president did in fact have express authority to bind the company. While perhaps the board would have preferred not to pay such a high percentage, there was no restriction on the president in dealing with the pharmacist.

Pursuant to this judgment, royalties will be paid by the company to the pharmacist, at the rate of 3.5%. R

Based on: *Bairlex laboratories v. Clobes*, 1992 Westlaw 232073 (September 23, 1992)

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# Personal Strategies

## *Disability Insurance and You*

*Peter A. Winer, Mayer Steinberg & Yospe*



Ask yourself a question. If you were in a hospital bed unable to work, and your insurance agent said if you'd sign a form he'd pay your salary, would you sign it?

Is there a moral here? Yes. Disability insurance is important. And the time to review your situation is now.

A disability lasts longer than 90 days and is three times more likely than death at almost every age under 65. Yet most of us own life insurance. And less than one third of pharmacists own adequate disability insurance. Every pharmacist in Maryland insures his or her car, home, and store. Yet the likelihood of collecting on even this important coverage is less than the risk of going out on a disability for 90 days. Disability insurance is one of the only benefits that you can provide for yourself that you aren't required to provide for any other employees. It is absolutely legal to provide disability insurance on a selective basis.

How long could your business afford to pay you, and the pharmacist that replaces you, when you're out disabled?

### **Structuring Your Coverage**

In designing your disability coverage to fit your personal situation there are three basic variables. How much monthly income do you need, how long can you wait before it starts and how long should you be paid.

Start with how much. Buy enough coverage to keep you in your home and able to pay your monthly bills. Figure out how much your monthly

fixed expenses are or what it would cost to hire a pharmacist to replace you and buy at least that much in monthly disability benefits.

Before you decide how long your benefits should begin, take a look at your savings and your business cash flow. How long are you willing or able to pay your fixed expenses with no income? Can your business continue to pay you if you can't work? Although the longer you wait before your benefits begin the lower the premium will be, the best value is a three month wait.

As to how long benefits should be paid, you should purchase the longest benefit period you can afford. Bear in mind that this is catastrophic coverage. You aren't insuring for short term problems, but rather for long term serious situations. Your benefits should be paid at least to age 65. And a lifetime benefit period makes sense if the cost is within your budget.

If you own your own practice, coverage is also available for business overhead expenses which will cover your business expenses. The cost for this is tax-deductible, and the policy covers business expenses, (except your salary) that you can write off on your business tax return. It's that simple. The cost for this coverage is very low compared to personal disability coverage because benefits are paid for only one or two years.

### **Definitions**

Once you've designed your plan, the most important part of the policy is the definitions section. Since what

constitutes a disability is so gray, the definitions in the policy are critical. Get a sample policy and read it before you buy. Look closely at the definitions of "Total disability", "Residual" or "Partial Disability" and "Sickness."

The definition of "Total Disability" should be what's known as "Own Occupation." It should say that you are disabled "if due to a sickness or injury you are unable to perform the substantial and material duties of your regular occupation and are under the care of a physician appropriate to your condition." If the care of a physician is required, without the word appropriate, beware. There was a recent case where a surgeon lost a finger, and of course was discharged by his physician. His benefits immediately stopped. Further, make sure that if you are unable to perform your occupation and you take another job, there are no clauses that will cause you to lose your benefits.

Partial and residual refer to a disability that caused your income to decrease although you may be able to

work. The definitions of "Partial" or "Residual" disability should not require you to have a "loss of time or duties." For example, a broken arm might slow you down, although you would probably be capable of working full time (no loss of time) and continue to dispense prescriptions (no loss of duties.) But this slowdown might cause a loss of revenue, and that's where a partial or residual disability benefit comes in. It pays you the pro-rata benefit equal to your loss of income. In English that means if your income is off by 50% the company would pay 50% of your monthly disability benefit.

The definition of "Sickness" should be an illness that is "diagnosed while your policy is in force." It should not say "which first manifests itself while your policy is in force." The "first manifest" clause can allow a company to deny benefits that might otherwise be payable. For example if you had a headache the year before your policy took effect, after which you were diagnosed with a brain tumor, benefits could be denied because the problem first manifested itself before

the policy took effect. Sound far-fetched? That is the unfortunately real example of a case in Maryland only a few years ago.

### **Don't Procrastinate**

Insure the goose that lays the golden eggs, your ability to earn an income. It's your ability to earn an income that makes all of the other assets in your life possible.

The time to review your disability coverage is now. Don't put it off. Costs increase with your age. And once you buy a disability policy, the rates are guaranteed forever. When was the last time you got that kind of a guarantee in writing?

There may never be a convenient time to start, but there will never be a better time to start than right now. For assistance in determining how to properly structure your coverage, call Mayer Steinberg & Yospe at (410) 484-7000. **R**

## **Pharmacists Helping Pharmacists**

Experts believe that 10% of Americans suffer from some form of chemical or alcohol problem. The disease of dependence knows no boundaries -- rich or poor, educated or illiterate, black or white are all victims.

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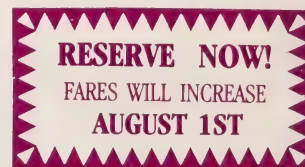
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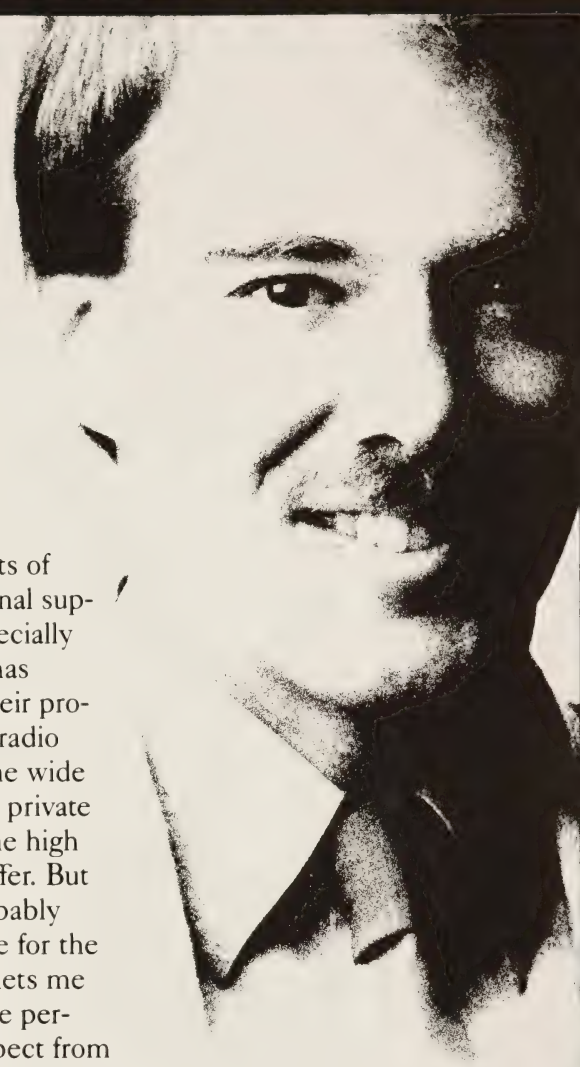
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NO. 8



*Eating Disorders*  
*When Body Image Becomes an Obsession*





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# President's Commentary

Howard R. Schiff, P.D., MPhA President



Writing this monthly article is one of the chores/pleasures of being President of MPhA. The nicest thing about it is that what I have to say won't be immediately rebutted. After all, comments and/or criticism of what I write has to at least wait for publication.

I've often heard it said that we pharmacists are always reacting to some situation. Certainly you've heard someone say, "If only pharmacy was proactive." In the community setting, it seems we're always responding, especially to customers. There's always a complaint: the price was too high, the service was too slow, I didn't want the generic, I don't want the brand. In a sense, pharmacists are right, we are constantly reacting.

But we react according to some preset group of standards which we knowingly or unknowingly have established. These standards vary from "The customer is always right" to something approaching, I'm sorry to admit, "The customer be damned". Using standards somewhere between those points, each of us approach the problem and make hopefully reasoned responses to solve the dilemma. *How* we arrive at as well as *what* those solutions are become characteristic of our pharmacy; they are what our patients, our customers have come to expect from us in difficult situations.

The fact that we are so highly respected in a time of great impersonality and poor service in all facets of retail business means that we are perceived as having high standards and have reacted to the public's satisfaction.

All of this brings me to the current problem facing pharmacy with CIGNA. Community pharmacists have been either denied entry to a closed network (kicked out to be more precise) or offered a "take-it-or-leave-it" contract at a ridiculously low reimbursement level. To add insult to injury, the termination letters sent by CIGNA were photocopied form letters. Frankly, I've seen junk mail with more personalization and, even if feigned, more interest in treating us with the respect we deserve.

According to a recent article in *The New York Times*, CIGNA is one the largest health payers in the country, and is set to be a big player when National Health Care Reform takes place. They along with Aetna, Metropolitan Life, Prudential, and Travelers are known as the "Gang of Five". They have formed an alliance to promote managed competition because, says Travelers, "It is one of our most attractive (profit) opportunities." CIGNA sees prospects for "improved revenue growth and better margins."

Again, according to *The New York Times*, the Clinton Administration is aware of this concentration of power and money. They are considering removing the antitrust exemption from the insurance industry. Certainly the industry's behavior towards community pharmacy justifies the step. Perhaps if the insurance companies learned something from us about standards in decision making, about how to treat clients, patients or customers, they could command more respect and still improve their bottom line.

R



# An Overview of Eating Disorders

## *Anorexia Nervosa, Bulimia Nervosa, and Related Disorders*

Amy Baker Dennis, M.A., L.P.C.C. and Randy Sansone, M.D.



### Clinical Characteristics

**Anorexia Nervosa** Anorexia nervosa is an eating disorder characterized by an intense drive for thinness, relentless dieting efforts, and extreme weight loss leading to emaciation and possible death. In classic anorexia nervosa, the weight loss results from calorie restriction, fasting, and exercise. While often seen as a problem of recent times, the term itself, "anorexia nervosa", was coined by clinicians over one hundred years ago. The disorder is a complex mixture of psychological and physical problems, but psychological issues are the cause for its development. It is estimated that perhaps one percent of adolescents develop this disorder and females predominate (90-95%).

Anorexia nervosa is accompanied by a variety of changes in the areas of behavior, thought, perception, mood, and social interaction. Notable behavioral changes center around food. The individual with anorexia often divides foods into "good" and "bad" categories, with good foods being hypocaloric (e.g., vegetables and fruits) and bad foods being hypercaloric (e.g., meats, carbohydrates, sweets). Hypocaloric foods are ingested and hypercaloric are avoided, which results in very low daily calorie levels. Food ingestion is often preceded by intense anxiety and the social pleasure of eating is lost. Mealtimes may be totally avoided or small amounts of food may take hours to be eaten.

Every act of eating appears to be governed by rules which may involve food placement on the plate, the time/location of eating, the number of

chews per bite, and the size of bites. Food is often dissected and relocated about the plate. The anorexic individual may enjoy cooking for others, being physically near food, and/or constantly be preoccupied with thoughts about food (e.g., dreaming about food, collecting recipes, storing/hording food).

Behavioral changes can also be observed in the anorexic's increasing preoccupation with his/her body. The individual with anorexia often becomes obsessed with observing the body, carefully scrutinizing it for changes resulting from weight loss (e.g., the flattening of the abdomen, visibility of the rib cage or hip bones, loss of fat in the buttocks). She/he may exercise relentlessly and weight themselves multiple times per day. Frequently, there is active comparison of their size and shape to others, and thin individuals may be perceived as a threat. Being considered "slight", "skinny", "tiny" or "petite" takes on unique personal value.

Anorexia nervosa is also accompanied by changes in thoughts, beliefs and attitudes. Dieting becomes the most important activity in the individual's life. Weight loss is equated with success, satisfaction, self-esteem and control. In most cases, there is an underlying fantasy that weight loss can cause or prevent some life event (e.g., prevent parental divorce, enhance athletic prowess, attract a boy/girlfriend, prevent changing schools or going to college). Concentration, decision-making, and judgement become impaired as weight loss progresses.

Perceptual changes also occur, the most dramatic being the distortion in

body image. The anorexic individual frequently overestimates his/her size and shape. Although body image distortion is not unique to anorexic individuals (i.e., it also occurs in routine dieters and pregnant women), it becomes more pronounced as starvation progresses. This distortion is probably caused by a combination of both psychological and biological factors.

The mood changes that accompany anorexia nervosa can often be dramatic. Irritability, depression, anxiety, jitteriness, and/or rapid mood shifts, are common in routine dieters but far more pronounced in individuals with anorexia nervosa.

As starvation progresses, social changes also take place. The anorexic tends to become aloof, withdrawn, and isolated. Peers may be the first to notice these changes. Initially, they may express concern and encourage the anorexic to eat, but subsequently, many abandon their troubled friend out of sheer frustration.

Finally, the starvation state in anorexia nervosa can result in a variety of physiological changes. The body reacts by conserving resources (i.e., metabolically slowing down and stopping those physiological processes which are not vital to the individual's survival). There may be a slowed heart rate, lowered body temperature, lowered blood pressure, diminished reflexes, slowed thyroid functioning, and an absence of the menstrual cycle in women. The body hair may become dry and brittle and there is often notable hair loss. "Lanugo", a fine downy hair, may appear on the body surface and the skin is frequently dry. Surprisingly, many individuals have restless energy and hyperactivity

despite significant starvation. The body has limits in its ability to tolerate chronic dieting and self-induced starvation. Mortality rates due to the complications of anorexia nervosa vary between 5-8%.

The focus of treatment in anorexia nervosa is two-fold: (1) weight restoration and (2) psychological restoration. The treatment setting is highly individualized but extreme weight loss (20-25%) usually requires inpatient treatment. A variety of treatment interventions may be appropriate including, individual psychotherapy, group therapy, family/couples counseling, nutritional counseling, and general education about the disorder. Engaging a mental health professional who is experienced in the treatment of anorexia nervosa is of extreme importance for psychological recovery. Treatment responses vary among patients. Approximately one-third recover completely, one-third demonstrate significant improvement and about one-third remain chronically ill. In general, early intervention is the best predictor of a good prognosis.

**Bulimia Nervosa** Bulimia nervosa is an eating disorder characterized by binge eating (i.e., the secretive ingestion of large amounts of calories, often carbohydrates or sweets, within a discrete period of time), which is followed by some form of compensation behavior (e.g., self-induced vomiting, laxative or diuretic abuse, diet pill abuse, fasting or chronic dieting, compulsive exercise to counter weight gain). Bulimia nervosa is prevalent in 1% to 2% of the adolescent population and approximately 90% of those with the disorder are female. It is not uncommon for individuals with anorexia nervosa to develop bulimia nervosa as well. As

many as one-third of the bulimic population has been previously anorexic.

The onset of bulimia nervosa is usually preceded by dieting that begins in adolescence. The severe restriction of dieting can lead to binge eating. Purging after a binge begins as a simple weight-control tactic. For many, however, purging escalates into repetitive cycles of binge-eating and purging. Most individuals experience exacerbations and remissions of this disorder and cycles may vary in frequency from occasional to multiple times per day. Bulimic episodes are frequently accompanied by feelings of isolation, self-deprecating thoughts, depressed mood, and low self-esteem. These episodes often intensify during times of personal stress.

Unlike the anorexic who is less aware of his/her eating dilemma due to body-image distortion and sense of personal mastery, the bulimic recognizes his/her abnormal eating behaviors. Indeed, there is often a great deal of conscious effort in planning, carrying out, and cleaning up after binge/purge episodes.

Binge eating voluminous quantities of foods seems to fulfill a variety of psychological needs such as, the need to soothe oneself, control frustration and anger, subvert sexual drives, and/or deal with loneliness. Purging may also function in this manner. Investigators are attempting to explore if there are any self-reinforcing biochemical processes at work, such as the release of endorphins.

Rigorous dieting and rigorous exercise are the most common methods of purging with self-induced vomiting a close third. Vomiting may occur spontaneously, but is often induced by the insertion of a finger or

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foreign object (e.g., food utensil, toothbrush). Vomiting can result in dental erosion (perimyolysis) due to the acidity of the gastric juices, electrolyte imbalances, salivary gland tenderness and enlargement, and the irritation of upper digestive system.

Laxative abuse is another common purging tactic. Laxatives are ingested either before or after a binge. Laxative abuse can result in abdominal discomfort, nausea, bloating, fluid loss, and electrolyte imbalances. If used regularly, they can destroy the physiological functioning of the lower digestive system (e.g., cathartic colon).

In the treatment of bulimia nervosa, a variety of interventions may be appropriate such as individual psychotherapy, group therapy, nutritional counseling, family/couples counseling, psychotropic medications, and general education about the disorder. The general goals of treatment are the normalization of eating patterns and daily calorie levels, the enhancement of coping skills, the heightening of self-awareness of personal needs, and the development of a solidified self concept. Hospitalization may become necessary to interrupt the binge-purge cycle, or treat severe depression or self-destructive behaviors, but is used less frequently than with anorexia nervosa. Outcome studies are less clear for bulimia nervosa, but in general, individuals with personality disorder and eating disorders have a more difficult time overcoming the eating disorder.

*Atypical Eating Disorders* Many individuals suffer from serious eating disorders but do not demonstrate meet all of the criteria for a formal diagnosis but display significant disturbance in their thinking and behavior around food, weight, shape and dieting. For example: (1) individuals that have all the features of anorexia nervosa except the loss of their menses; (2) individuals that have all the features of anorexia nervosa but are not 15% below normal body weight; (3) individuals that do not binge eat but self-induce vomiting to maintain or lose weight; (4) individuals that

## ***Eating Disorders Warning Signs***

### ***Anorexia Nervosa***

- Significant or extreme weight loss (at least 15% with no known medical illness).
- Reduces food intake.
- Develops ritualistic eating habits such as cutting up meat into extremely small bites, chewing every bite a large number of times.
- Denies hunger.
- Becomes more critical and less tolerant of others.
- Exercises excessively (hyperactive).
- When eating, only very low fat and low calorie foods.
- Says he/she is too fat, even when this is not true.
- Has highly self-controlled feelings.
- Does not reveal feelings.

### ***Bulimia Nervosa***

- Makes excuses to go to the restroom after most meals.
- Has mood swings.
- May buy large amounts of food and then suddenly it disappears.
- Unusual swelling around the jaw.
- Weight may be within normal range.
- Frequently eats large amounts of food, often high in calories (a binge) and does not seem to gain weight.
- May decide to purchase large quantities of food and eat it on the spur of the moment.
- Laxative or diuretic wrappers found frequently in the trash can.
- Unexplained disappearance of food in the home or residence hall setting.

### ***Both Anorexia & Bulimia and Related Eating Disorders***

- Makes excuses to skip meals and does not eat with others.
- Develops a tendency to be perfect in almost everything.
- Conversation is mostly focused on foods or around body shape.
- Often hears other peoples' problems but does not share his/her own.
- Is highly self-critical.
- Worries about what others think.
- Thinks about weight and body shape most of the day.
- Begins to isolate more from friends and family.
- The odor of vomit is in the bathroom regularly.

The more warning signs a person has, the higher the probability that the person has or is developing an eating disorder.

Adapted from The National Anorexic Aid Society

meet all the features of bulimia nervosa except the frequency of binge eating episodes; (5) individuals that meet all features of bulimia nervosa but do not engage in purging behavior, etc. Treatment for atypical eating disorders is the same as the treatment described above for anorexia nervosa and bulimia nervosa.

### **Multi-Determined Nature of Eating Disorders**

There is no single event or factor that causes an eating disorder, but most professionals agree that dieting (the conscious restriction of food intake) proceeds the onset of an eating disorder. It is also important to note that most individuals who diet do not develop full-blown eating disorders. Researchers have identified certain genetic, biological, psychological, personality, sociocultural and familial factors that may contribute to the onset of an eating disorder.

Genetic research has focused on family risk studies and twin studies. Family risk studies strongly suggest that eating disorders tend to run in families. In other words, relatives of an individual with anorexia nervosa or bulimia nervosa are more likely than the general population to develop an eating disorder. Twin studies are less conclusive, but in general, there is a high concordance rate for anorexia nervosa in identical twins which suggests either a genetic predisposition or environmental induction in the pathogenesis of an eating disorder.

Biological researchers suggest that there may be a problem with central nervous system neurotransmitters. Other researchers believe the brain chemistry may be involved because of the dramatic decrease in binge-eating that some bulimia patients experience after relatively short trials on antidepressant medication.

There has been a great deal of research conducted on the psychological and personality factors that may contribute to an individual's vulnerability to an eating disorder. Briefly,

some of the factors which may distinguish individuals who go on a diet and develop eating disorders from those that do not include: high need for perfectionism; significant adolescent turmoil; impaired self-concept and/or body concept; difficulty with identity formation; poor impulse control; affective over control and intolerance; and a relative absence of adaptive functioning to the maturational tasks of adolescence.

The sociocultural pressures on today's adolescents and young women to be thin and attractive also play an important role in the development of eating disorders. Historically, culture has dictated the desired feminine form. Seventeenth century paintings by Rubens reflect the images of full-bodied women. Plumpness was considered sexually desirable and a sign of fertility, strength and wealth. In the 1950's, large breasted women with curvaceous shapes became fashionable, but by the late 1960's the "Twiggy" look (i.e., flat chested, an extremely thin child-like body) became the new standard. Thinness in today's society is associated with self-control, attractiveness, intelligence, happiness, wealth and success. The media, fashion and the diet industry exploit this myth by bombarding us with products and services designed to push us toward losing weight. As a result, it is not surprising to find that adolescents who are undergoing uncontrollable body changes and the onset of new emotional and sexual drives, seek dieting in order to enhance their sense of self-control and acceptance by others. Males experience expectations for thinness through some sports, such as wrestling - where they purge to make a lower weight class.

Finally, researchers have identified several familial factors which may put individuals at greater risk for the development of eating disorders. They have found that first and second degree relatives of individuals with anorexia nervosa and bulimia nervosa have an increased incidence of depression and bipolar (manic-depres-

sive) illnesses, alcohol and substance abuse problems, and eating disorders. Therefore, individuals who diet and have a family history of alcoholism, and other forms of chemical dependency, depression and/or eating disorders may be at an increased risk to develop anorexia nervosa or bulimia nervosa.

### **Medical Complications in Eating Disorders**

A variety of physical signs and symptoms may develop in individuals with eating disorders. These may be due to the effects of one or more of the following: (1) calorie deprivation leading to weight loss and starvation; (2) the particular method(s) of weight control; and/or (3) accompanying psychological states (e.g., depression, anxiety).

The common physiological changes that accompany weight loss and starvation states are shown in figure A. These changes vary from individual to individual and are dependent on the age of the patient, the rapidity of weight loss, and the amount of weight lost. The body attempts to conserve energy (i.e., become hypometabolic) and eliminate non-vital functions (e.g., menstruation).

The methods employed to lose weight may also cause medical complications. Several commonly used methods and their accompanying complications are outlined in Figure B. Combinations of these methods may dangerously affect potassium regulation and fluid balance. Potassium depletion may result in fatigue, muscular cramps, and weakness. If the depletion is significant, heart arrhythmias (i.e. irregular heart beat) may develop which can possibly result in death. If potassium depletion is chronic, the kidneys may be damaged.

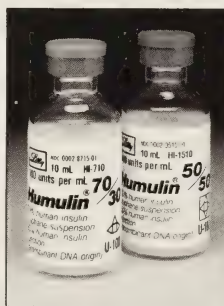
Underlying psychological states such as depression and/or anxiety can also cause physiological problems. Depression and stress may result in the cessation of menstrual periods. Clinically, patients with anorexia nervosa often report the disorder.




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Complicating the assessment of an underlying psychological state is the finding that depression accompanies starvation and is often found in anorexia nervosa and bulimia nervosa due to the presence of calorie deprivation.

Multiple physiological signs and symptoms may develop in persons with eating disorders. These may be due to weight loss, the weight control methods employed, and/or underlying psychological states.

### **Treatment Alternatives**

Individual psychotherapy is usually the foundation upon which the treatment experience begins. However, successful treatment of the eating disorder patient requires intervention on multiple levels and is highly individualized. Treatment usually begins with a medical evaluation. Following assessment, a variety of therapeutic interventions may be employed including individual psychotherapy, family therapy, marital/couples therapy, group therapy, support groups, chemotherapy, nutritional counseling and hospitalization.

**Medical Evaluation** Most outpatient and all inpatient eating disorder programs require new patients to receive a complete medical evaluation during the initial assessment phase of treatment. There are several reasons behind this practice including: (1) to assess for physical damage due to the eating disorder (e.g. cardiac dysfunction, electrolyte imbalances); (2) to insure that there are not other physical causes of the weight loss or vomiting; (3) to assess for other medical problems that the patient may have (e.g., heart murmurs, chemical dependency, ulcers, pregnancy); (4) to evaluate the need for hospitalization; and (5) to provide ongoing medical backup to the mental health professional. In general, medical evaluations require at least a complete general physical and a laboratory assessment, but may be far more extensive including an EKG.

### **Individual Psychotherapy**

Individual psychotherapy is generally recommended for all eating disorder patients. Within this treatment format, the individual is able to begin exploring attitudes about weight, shape and appearance. As the therapeutic relationship progresses, the content of the sessions usually shifts away from food and weight concerns to the underlying issues that precipitated and maintain the eating disorder. Typically, the individual discovers that they have faulty beliefs about the meaning of weight, shape and appearance which has lead them to the relentless pursuit of thinness. They frequently identify problems in relationships with their family and friends, or realize that they have great difficulty confronting and expressing negative emotions.

Individual psychotherapy provides a sheltered environment where the patient can explore their concerns, learn problem solving, decision-making, and assertiveness skills, test new behaviors, and receive constructive and non-judgmental feedback. This process promotes maturation, growth and independence. The frequency of sessions and the length of treatment is highly variable and should be based on the individual's needs. In general, treatment is complete when the patient has: (1) normalized eating patterns; (2) eliminate binge eating and purging and/or restored body weight to normal; (3) regained biological normalcy (e.g., restoration of menses, normal electrolyte balance); and (4) make the shift away from evaluating self-worth based on weight, shape and appearance, understood the underlying issues which precipitates and maintained the disorder.

**Family Therapy** Family therapy can be significant treatment for patients with eating disorders. In some situations, one therapist may see the eating disorder patient and another see the family; in others, co-therapists may work together with the family. The frequency of sessions and the length of treatment are mutually agreed upon by the therapist and

family and based on the patient's needs.

Family therapy provides an arena for the therapist to: (1) assess the impact of the eating disorder on the family; (2) observe communication and decision-making patterns; (3) observe conflict management styles; (4) discover roles within the family; (5) uncover family myths, ideologies and values; and (6) provide basic information about the treatment of eating disorders and the recovery process. The primary goal of treatment is to improve overall family functioning, which in turn, facilitates the recovery of the individual.

Family therapy is often a useful adjunct for adolescents, and periodic family sessions may be particularly helpful to the young adult who is struggling with separation from the primary family.

### **Marital/Couples Therapy**

Marital/Couples Therapy is indicated when there is significant conflict in the couple's relationship, whether due to the personalities involved, the eating disorder, or a combination of the two. This may involve the parents of an individual with an eating disorder, or the patient and his/her significant other. The purpose of couples therapy is to strengthen the relationship bond and to assist the couple in problem solving and conflict resolution. Periodic couples sessions may be useful in identifying emerging relationship issues, improving communications skills and providing information about the treatment and recovery process.

**Group Psychotherapy** Group psychotherapy has been found to be an effective form of treatment for some eating disorder patients. Psychotherapy group help to: (1) demystify the disorder; (2) diminish feelings of isolation and secrecy; (3) facilitate realistic goal setting; (4) increase knowledge of successful recovery techniques; (5) improve the expression of feelings; (6) increase one's social support network; and (7) increase problem-solving, decision

making and assertiveness skills.

Psychotherapy groups may be ongoing or time limited, membership may be closed or participants may join at any time, and the frequency and duration of sessions varies. Therapy is provided by trained professionals and the focus is on individual dynamics and group process.

**Support Groups** In general, support groups are free of charge, anonymity is preserved and members may enter or leave the group at any time. Support groups usually serve as an adjunct to professional care and are not considered a primary form of treatment. Support groups provide information to individuals and families about what initiates and maintains an eating disorder as well as appropriate treatment methods and providers. The group can also be a valuable support system for individuals who have become completely isolated by their eating disorder. Support group facilitators may be professional counselors, recovered individuals or family members of anorexic/bulimic individuals. The foundation of support groups is the sharing of experience.

**Chemotherapy** Antidepressants have been found effective in the treatment of some eating disorder patients. In severely starved and malnourished anorexics, medication is typically avoided due to the increased sensitivity to side effects and potentially serious complications from cardiac arrhythmias and blood pressure fluctuations. In addition, drug kinetics and metabolism are somewhat unpredictable in a starved individual and unexpected complications may arise. Re-feeding the starved anorexic may alleviate the signs and symptoms of depression, if present.

The use of antidepressant medication as an adjunct in the treatment of bulimia nervosa and some atypical eating disorders is relatively common today. The following issues should be considered prescribing medication: (1) the type of depression; (2) the type and frequency of weight control methods employed; (3) alcohol or

### **Possible Medical Complications of Commonly Used Weight-regulation/Weight-loss Methods**

#### **Vomiting**

- Parotid gland enlargement (neck area)
- Erosion of tooth enamel and increased cavities
- Tears in esophagus
- Chronic esophagitis
- Chronic sore throats
- Difficulty swallowing
- Stomach cramps
- Digestive problems
- Anemia
- Electrolyte imbalance

#### **Diuretic Abuse**

- Hypokalemia (low potassium). If severe, possible cardiac arrhythmia; if chronic, serious kidney damage.
- Fatigue
- Diminished reflexes
- Fluid loss: dehydration, light headedness, thirst

#### **Laxative Abuse**

- Non-specific abdominal complaints (cramping, constipation)
- Sluggish bowel functioning ("cathartic colon")
- Malabsorption of fat, protein and calcium

Combinations of these methods can dangerously effect potassium regulation and fluid balance.

substance abuse; (4) metabolic status (*ie*, potassium levels); (5) the patient's abuse potential; (6) family history of depression; and (7) history of previous treatment failures. Laboratory evaluations prior to initiating chemotherapy may uncover metabolic, nutritional, and preexisting medical abnormalities. Standard medical practice dictates observing the routine precautions when prescribing any medications.

#### **Inpatient Hospitalization**

Hospitalization may become necessary for the eating disorder patient. In general, inpatient care should be considered when: (1) weight loss continues after a reasonable period of time in outpatient treatment; (2) the individual is unable to break the binge-purge cycle after a reasonable period of time in outpatient treatment; (4) there is a metabolic crisis

especially hypokalemia (loss of potassium); (5) there are signs of psychiatric decompensating (severe depression, suicidal ideation, self-destruction behavior, etc.); (6) the individual needs to be separated from the family or environment before healthy behavior patterns can be established.

There are several alternatives available for persons needing inpatient care, including: (1) medical ward of a general hospital; (2) psychiatric ward of a general hospital; (3) psychiatric hospital or psychiatric hospital; (5) eating disorder unit of an addiction or substance abuse facility; (6) residential treatment program.

The inpatient program for the emaciated anorexic is generally multi-dimensional. It typically involves behavior modification, individual (and

Continued on page 25....



## Pharmacy's Role in Managed Care

*Robert C. Johnson, P.D., President, PCS, Inc.*



No other issue has captured the attention of the American public in recent times like health care reform. It is impossible to pick up a newspaper from New York to Los Angeles without seeing at least one article on health care. The President has determined that health care reform is his highest priority and, of course, has empowered Hillary to make it happen.

Why all of this interest in health care? It actually began in the early '80s when health care costs began to rise excessively. You will recall the pharmaceutical manufacturers, at that time, began to raise drug prices at two or three times the rate of inflation. Hospital, medical and other health expenditures increased proportionately. Corporate America began to experience expenditures for health exceeding most other overhead expenses (except labor) and they were determined to do something about it.

### **Reimbursement Pressures**

In the mid '80s, we saw the proliferation of business/labor coalitions and pressures began to mount on insurance carriers and third-party administrators to reduce health care costs. The most immediate way of impacting costs was to reduce provider reimbursement. The pressure was first applied to hospitals as we witnessed the implementation of DRGs. While the hospital industry predicted doom and gloom, actually the more innovative institutions learned how to cope with DRGs and, in fact, have survived rather well.

Next, the attention was turned to physicians and we witnessed the growth of HMOs and the emergence

of preferred provider organizations (PPOs). Doctors found it necessary to join these organizations and discount their fees to retain their patient base. This was a new phenomena for the medical profession and not one appreciated by practicing physicians. Nonetheless, they saw the marketplace changing and those who wished to remain in health care delivery had to change along with it.

At the turn of the decade, health care purchasers and administrators began to direct their attention at the rising cost of pharmaceuticals. Drug product costs rose nearly 50% from 1987 to 1990. During this same period, pharmacists' fees remained constant. Unable to get to the manufacturers to impose cost controls, buyers applied pressure on the pharmacists through the lowering of drug ingredient costs or the reduction of Average Wholesale Prices (AWPs). Pharmacists, seeing their profits shrink, responded as did hospitals and physicians before them. But, as hospitals and doctors realized, in order to retain their business, it became necessary to accept these cost containment programs. What has resulted is a health delivery system that no one in this country is particularly pleased with.

Hospitals have closed or converted to long-term care facilities. Physicians have left practice or have given up solo practice to join groups to maintain an acceptable level of income. The impact has been felt on pharmacy as well. Some chains have been forced into Chapter 11, while others have seen their profits dwindle. Independents are going out of business, either closing or selling to chains at the rate of 8% a year.



## Patient Access Issues

The revolution in health care has changed the American scene significantly in recent years and will continue to do so. Patients will travel further when requiring hospital services. They may find their physician has signed up with a group and is no longer available to them and, unless their pharmacist is participating in a network contracted by their health plan, they may have to seek another pharmacist; or much worse, be subjected to mail-order drugs.

Today's challenge to insurance carriers and health care administrators (e.g., PCS Health Systems) is to balance access to care with competitive cost. Payors are determined to lower health costs, but they also want to maintain reasonable access to care. In the instance of pharmacy services, most buyers want a pharmacist within three miles of the patient's residence.

## Enhancing Quality of Care

You might ask, "What about the quality of care a patient receives? Does anyone care?" Well, yes and no. Certainly, no payor wants his employee subjected to inferior care. But, has anyone really defined quality care? Let's take pharmacy, for example. What is quality care? Some would suggest that it merely implies that the right drug has been dispensed. This certainly appears to be the only criteria for mail-order pharmacy. Does the patient receive adequate consultation regarding his or her drug therapy? No. Consultation is rarely received from the physician and not often enough from the

pharmacist.

Although many pharmacists, both independent and chain, do provide an excellent consultation service, what about selection of the appropriate therapy? How many pharmacists make a concerted effort to assure that the drug being prescribed and dispensed is the most appropriate and cost-effective medication? Would there even be a need today for drug utilization review if every pharmacist assumed the responsibility to assure that his/her patients were receiving the least costly, yet most effective, medication? And, what about monitoring for compliance? We've all read the statistics that approximately 50% of all prescription medication is not properly taken. We know that 10% to 15% of hospital admissions are caused by adverse drug reactions and that approximately 25% of all prescriptions written are never filled.

There, indeed, is a very significant role that pharmacists can and will play in assuring quality health care at the most reasonable cost. That is not occurring frequently enough today—either because insufficient numbers of pharmacists are making it happen.

## Future of Pharmacy Practice

There is grave concern today in the pharmacy community, and there should be, with regard to the future of pharmacy practice. Will pharmacy, as we have known it in the past, continue? Not likely. Just as the solo practice of medicine is disappearing, a similar situation is occurring in pharmacy practice.

This does not mean that pharmacists will not continue to practice in

independent settings; but those who are will find it necessary to broaden their practice to include long-term care, home health care and other specialty practice opportunities. Likewise, chains will find it necessary to become more service-oriented, looking for niche-market opportunities.

Medication will soon be distributed in unit-of-use packaging, as is the case throughout the world. Consequently, payors will find it difficult to justify compensating pharmacists at existing rates to distribute prepackaged medications. Pharmacists (independent and chain) who are primarily distributors and not health care practitioners, will find it difficult to continue in business. While managed care today has primarily focused on managing cost this, too, will change the health care system in transitioning from diagnosis and treatment patterns to outcome measurements, based on extensive use of information.

But, before moving into the future, let's examine more carefully where pharmacy is today. As we have indicated, and as NARD Past President Bill Katz has stated, "managed care, at this time, is little more than managed cost." Payors have sought to reduce their health care expenditures with minimal concern on overall results.

Pharmacists, consequently, have been caught up in the cost-squeeze dilemma. Pharmacists have not been responsible for the excessive increase in drug product prices; yet, pharmacists have borne the brunt of the attempts to reduce those product

Continued on page 18....

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One 10 mg CLARITIN Tablet provides round-the-clock relief.

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\* In studies with CLARITIN Tablets at doses 2 to 4 times higher than the recommended dose of 10 mg, a dose-related increase in the incidence of somnolence was observed.

† Relief began in 13% of treated patients vs 4% of placebo-treated patients within 30 minutes ( $P=0.04$ ). At 2 hours, 48% of patients receiving placebo experienced relief. Distribution of onset times was significantly earlier for CLARITIN Tablets vs placebo ( $P=0.03$ ).

Please see brief summary of full Prescribing Information on reverse side.



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**INDICATIONS AND USAGE**  
CLARITIN Tablets are indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis.

**CONTRAINDICATIONS**  
CLARITIN Tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients.

**PRECAUTIONS**  
**General:** Patients with liver impairment should be given a lower initial dose (10 mg every other day) because they have reduced clearance of CLARITIN Tablets.

**Drug Interactions:** Drugs known to inhibit hepatic metabolism should be coadministered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received macrolide antibiotics, ketconazole, cimetidine, ranitidine, or theophylline along with CLARITIN Tablets in controlled clinical trials is too small to rule out possible drug-drug interactions. There does not appear to be an increase in adverse events in subjects who received oral contraceptives and CLARITIN Tablets compared to placebo.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** In an 18-month oncogenicity study in mice and a 2-year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg (mice) and 25 mg/kg (rats). In the carcinogenicity studies, pharmacokinetic assessments were carried out to determine animal exposure to the drug. AUC data demonstrated that the exposure of mice given 40 mg/kg of loratadine was 3.6 (loratadine) and 18 (active metabolite) times higher than a human given 10 mg/day. Exposure of rats given 25 mg/kg of loratadine was 28 (loratadine) and 67 (active metabolite) times higher than a human given 10 mg/day. Male mice given 40 mg/kg had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg. The clinical significance of these findings during long-term use of CLARITIN Tablets is not known.

**Mutagenicity studies:** there was no evidence of mutagenic potential in reverse (AMES) or forward point mutation (CHO-HGPRT) assays, or in the assay for DNA damage (Rat Primary Hepatocyte Unscheduled DNA Assay) or in two assays for chromosomal aberrations (Human Peripheral Blood Lymphocyte Chromosome Assay and the Mouse Bone Marrow Erythrocyte Micronucleus Assay). In the Mouse Lymphoma Assay, a positive finding occurred in the nonactivated but not the activated phase of the study.

Loratadine administration produced hepatic microsomal enzyme induction in the mouse at 40 mg/kg and rat at 25 mg/kg, but not at lower doses.

Decreased fertility in male rats, shown by lower female conception rates, occurred at approximately 64 mg/kg and was reversible with cessation of dosing. Loratadine had no effect on male or female fertility or reproduction in the rat at doses of approximately 24 mg/kg.

**Pregnancy Category B:** There was no evidence of animal teratogenicity in studies performed in rats and rabbits. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CLARITIN Tablets should be used during pregnancy only if clearly needed.

**Nursing Mothers:** Loratadine and its metabolite, descarboethoxyloratadine, pass easily into breast milk and achieve concentrations that are equivalent to plasma levels with an AUC<sub>0-12h</sub>/AUC<sub>0-24h</sub> ratio of 1.17 and 0.85 for the parent and active metabolite, respectively. Following a single oral dose of 40 mg, a small amount of loratadine and metabolite was excreted into the breast milk (approximately 0.03% of 40 mg over 48 hours). A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when CLARITIN Tablets are administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children below the age of 12 years have not been established.

**ADVERSE REACTIONS**

Approximately 90,000 patients received CLARITIN Tablets 10 mg once daily in controlled and uncontrolled studies. Placebo-controlled clinical trials at the recommended dose of 10 mg once a day varied from 2 weeks' to 6 months' duration. The rate of premature withdrawal from these trials was approximately 2% in both the treated and placebo groups.

REPORTED ADVERSE EVENTS WITH AN INCIDENCE OF MORE THAN 2% IN  
PLACEBO-CONTROLLED ALLERGIC RHINITIS CLINICAL TRIALS  
PERCENT OF PATIENTS REPORTING

	<b>LORATADINE</b> 10 mg QD n = 1926	<b>PLACEBO</b> n = 2545	<b>CLEMASTINE</b> 1 mg BID n = 535	<b>TERFENADINE</b> 60 mg BID n = 984
Headache	12	11	8	8
Somnolence	6	6	22	9
Fatigue	4	3	10	2
Dry Mouth	3	2	4	3

Adverse event rates did not appear to differ significantly based on age, sex, or race, although the number of non-white subjects was relatively small.

In addition to those adverse events reported above, the following adverse events have been reported in 2% or fewer patients.

**Autonomic Nervous System** Altered salivation, increased sweating, altered lacrimation, hypohidrosis, impotence, thirst, flushing.  
**Body As A Whole** Conjunctivitis, blurred vision, earache, eye pain, tinnitus, asthma, weight gain, back pain, leg cramps, malaise, chest pain, rigors, fever, aggravated allergy, upper respiratory infection, angioneurotic edema.

**Cardiovascular System** Hypotension, hypertension, palpitations, syncope, tachycardia.

**Central and Peripheral Nervous System** Hyperkinesia, blepharospasm, paresthesia, dizziness, migraine, tremor, vertigo, dysphonia.

**Gastrointestinal System** Abdominal distress, nausea, vomiting, flatulence, gastritis, constipation, diarrhea, altered taste, increased appetite, anorexia, dyspepsia, stomatitis, toothache.

**Musculoskeletal System** Arthralgia, myalgia.

**Psychiatric** Anxiety, depression, agitation, insomnia, parosmia, amnesia, impaired concentration, confusion, decreased libido, nervousness.

**Reproductive System** Breast pain, menorrhagia, dysmenorrhea, vaginitis.

**Respiratory System** Nasal dryness, epistaxis, pharyngitis, dyspnea, nasal congestion, coughing, rhinitis, hemoptysis, sinusitis, sneezing, bronchospasm, bronchitis, laryngitis.

**Skin and Appendages** Dermatitis, dry hair, dry skin, urticaria, rash, pruritus, photosensitivity reaction, purpura.

**Urinary System** Urinary discoloration, altered micturition.

In addition, the following spontaneous adverse events have been reported rarely during the marketing of loratadine: peripheral edema; abnormal hepatic function including jaundice, hepatitis, and hepatic necrosis; alopecia; seizures; breast enlargement; erythema multiforme.

**OVERDOSAGE**

Somnolence, tachycardia, and headache have been reported with overdoses greater than 10 mg (40 to 180 mg). In the event of overdose, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

Treatment of overdose would reasonably consist of emesis (ipecac syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or if comatose, gastric lavage should be performed with normal saline. Saline cathartics may also be of value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if loratadine is eliminated by peritoneal dialysis.

Oral LD<sub>50</sub> values for loratadine were greater than 5000 mg/kg in rats and mice. Doses as high as 10 times the recommended clinical doses showed no effects in rats, mice, and monkeys.

 Schering Corporation  
Kenilworth, NJ 07033 USA

costs. Pharmacists have not appreciated efforts to reduce those costs, where it has been at their expense - and this is understandable. Yet, as this emphasis on drug cost reduction has occurred in the past three to four years, pharmacists have not adequately responded by shifting these reduction efforts to the manufacturer. For example, the conversion to generics is only occurring an average of 28% to 30% of the time, when the generic interchange should be closer to 50%. The difference in the cost of a brand-name product and a generic, to a payor, is approximately \$30 per prescription, on average. This is a significant, unnecessary cost to a plan sponsor.

Additionally, little effort is made to contact the physician to encourage a lower cost antibiotic when an expensive one is prescribed. Again, this shifts an unnecessary and significant cost to the payor.

These responsibilities to lower cost must be assumed by pharmacists who expect to play a role in the evolving health care system. Should pharmacists then be compensated for their intervention to achieve lower cost? Absolutely. The profession should insist on this, rather than chasing the rainbows of the past.

Many pharmacists have been upset with our attempt to create a competitive marketplace situation wherein pharmacists can continue to serve their patients; albeit, in a more controlled environment.

Actually, the reason that mail-order pharmacy is not enjoying the accelerated growth this year that it has experienced in the past, is because of the growing competitiveness of the retail pharmacy marketplace. While pharmacists have not appreciated the discounted AWP situations that confront them, the fact remains that the economic pressures brought to bear on community pharmacy (chains and independents), has stemmed the tide of mail order and now offers the opportunity to return much of that lost business to the local pharmacy.

## Growing Competitiveness

If pharmacists will participate in competitive networks, increase generic usage and agree to dispense maintenance quantities of drugs at prices competitive to mail-order pricing, and offer personalized services; then, unquestionably, the growth of mail order will be stopped in its tracks. We are seeing the trend develop. Reports indicate that in today's competitive retail situation, the price of a prescription is no more expensive at the community level and may be even less than mail order.

Yes, there are still price differentials as a result of the drug industry catering to select purchasers, such as mail order. But, if organized pharmacy, with the support of Senator Pryor, continues to apply the pressure to eliminate multi-tiered pricing or, at least, make it available to all purchasers, the playing field could be leveled and pharmacies in the community setting will be able to compete even more effectively.



Keep in mind that this increased retail competitiveness through discounted AWP's, generic usage, and maintenance dispensing plans - as limited as they still are - has curbed mail-order growth and is making it possible for those pharmacists who understand and are responding to marketplace demands to stay in business. While we are criticized for causing this to happen, I'll take that short-term abuse because, in the long run, if community pharmacy is to survive it will be as a result of forced marketplace changes necessary today for future survival opportunities.

### Health Care Reform

Now let's turn to what that future might have to offer.

First, I question that we will see significant health care reform occur in our country, as proposed by the Clinton Administration, simply because neither Congress nor the Administration can find a way to pay for a universal health care system.

I'm not convinced that the health care system should be reformed if it results in a government-controlled health care environment. I believe that President Clinton is achieving his goal by keeping health care reform as a priority item. He is causing the insurance industry, health care administrators, pharmaceutical manufacturers, state governments and providers to accept change as a requirement and to implement that change without the necessity of federal government intervention.

We are experiencing, already, a tremendous shift from indemnity health coverage to managed indemnity alternatives that are competitively structured and competitively priced.

CommunityPurchaseOrganizations (CPOs) are being formed across the nation to establish partnerships with

health care providers to offer health services that are competitively priced and easily accessible.

### Pharmacists as Health Managers

Pharmacists have an extraordinary opportunity to become actively involved in these community organizations. Pharmacists must come to the table, not as dispensers, but as integral managers of patient care. Pharmacists must be willing to assume responsibility to interface with the physician and assist in the selection of the most cost-effective, rational therapy for the patient. They must be willing to counsel and monitor patients to assure the achievement of desired outcomes. Pharmacists must be willing to abandon the present reimbursement system, which is tied to product dispensing at fictitious wholesale prices (AWP) - which incidentally, has led to the economic ruin of pharmacy, and insist, instead on being compensated for the savings that are realized through the value-added services they deliver.

Will pharmacy leaders stand up to this challenge? Will individual pharmacists accept a changing role in a changing economic environment?

The future is now. There is not time to continue the hand-wringing and the wishing for the past. Those good old days will never return. If pharmacists stand by and wait for someone else to solve their problems and keep them in business, they simply won't survive because everyone else is in the same boat.

Physicians, nurses, hospitals, pharmacists, insurance and health care administrators are all facing up to the reality that our health care system in America is undergoing a revolutionary transition; one that is necessary in order for all American citizens to receive good health care in a system

that will neither bankrupt the nation nor bankrupt the American corporations who provide the economic viability for our country's future.

### Managed Care Technology

The electronic highway is a reality today in health care administration. PCS' movement into hospital and medical claims administration provides us with the opportunity to link hospitals, physicians, pharmacists, patients and plan sponsors. This means that right at the point-of-service in the doctor's office, decisions can and will be made that will assure, to the greatest degree possible, the appropriateness of the prescribed treatment. PCS is a leader in the revolution to reduce the outrageous administrative costs that prevail throughout the health care system. As this electronic highway evolves, some health care providers will find it threatening, as is always the case; especially in this high-tech environment that we now live in.

I strongly urge pharmacists to see beyond the present and imagine and prepare for the opportunities that a new high-tech health care delivery system has to offer. Pharmacy will not be practiced in 2000 and beyond as it is today. In fact, it won't even resemble pharmacy practice today. Yet, far too few are preparing to participate in the opportunities that await enlightened health care practitioners in the next century.

I urge you to become one who can see the future, who prepares for it and who will reap its benefits. **R**

*Editors Note:* This presentation was given by Robert C. Johnson before the Alabama Pharmaceutical Association Annual Meeting in Panama City, Florida, June 26, 1993.



# Drug Information Questions

## *Prophylaxis of *Pneumocystis carinii* Pneumonia*

Tammi Tice, Pharm.D., Babette Prince, Pharm.D., UMAB Drug Information Center

This article provided under a grant-in-aid from **Glaxo**

### *Drug Information Request*

With Maryland ranking sixteenth in cases of HIV and AIDS, I am seeing more and more patients being treated for the prevention of opportunistic infections, especially *Pneumocystis carinii*. What is the value of preventive therapy?

### *Response*

*Pneumocystis carinii* pneumonia (PCP) has been the most common life-threatening opportunistic infection (OI) in patients with human immunodeficiency virus (HIV) infection, however, with the advent of primary prophylaxis the incidence of PCP has fallen. Mortality increases with each subsequent episode of PCP and, left untreated, carries a mortality rate of 100%. Since PCP is the most common OI in patients with HIV infection, primary prophylaxis is recommended, while secondary prophylaxis is necessary for the prevention of recurrent infection.<sup>1-10</sup>

Lifelong prophylaxis is warranted for patients with HIV infection. The indications for receiving PCP prophylaxis include one or more of the following: (1) a CD4 count < 200 cells/mm<sup>3</sup> (preferably on two separate occasions); (2) the development of persistent unexplained fevers (>100° F for at least two weeks) regardless of the CD4 count; (3) development of unexplained oropharyngeal candidiasis regardless of CD4 count; (4) the development of another OI regardless of CD4 count; (5) or if the patient develops and recovers from an episode of PCP.<sup>4,5,10</sup>

### **TMP/SMX Regimens**

The most common prophylactic regimens include trimethoprim/sulfamethoxazole (TMP/SMX) and aerosolized pentamidine. Other prophylactic regimens have shown promise for PCP including daily dapsone, dapsone in combination with pyrimethamine taken weekly, dapsone in combination with trimethoprim, sulfadoxine in combination with pyrimethamine taken once or twice weekly, and atovaquone. At this time, however, there is insufficient data to provide a firm foundation for their recommendation. These agents may be considered in patients who are intolerant to both TMP/SMX and aerosolized

pentamidine.<sup>4,9,11</sup>

TMP/SMX is the agent of choice for primary and secondary prophylaxis because it is efficacious, has good oral bioavailability, is generally well tolerated, and is active against other pathogens that often cause concomitant infections. This combination drug functions by inhibiting purine synthesis. Sulfamethoxazole inhibits the conversion of para-aminobenzoic acid to dihydrofolic acid, while trimethoprim blocks the conversion of dihydrofolic acid to tetrahydrofolic acid by dihydrofolate reductase inhibition. Through these steps, the biosynthesis of the nucleic acids essential to *Pneumocystis carinii* is inhibited.<sup>4,12</sup>

Minor adverse reactions with TMP/SMX include mild skin rashes, low-grade fever, nausea, and anemias. These effects are rarely life-threatening and prophylactic dosing can often be maintained. More severe adverse reactions include leukopenia, granulocytopenia with fever, rash, pruritus, intractable nausea and vomiting, and hepatitis. It must also be kept in mind that other variables such as another OI, neoplasms, concomitant drugs, as well as the disease state itself may contribute to these effects, therefore, TMP-SMX is not always the cause. The prophylactic regimen currently recommended is one double strength TMP-SMX tablet daily. However, a dose of one double strength tablet three times per week may also be effective.<sup>1,5,11</sup>

### **Pentamidine Regimens**

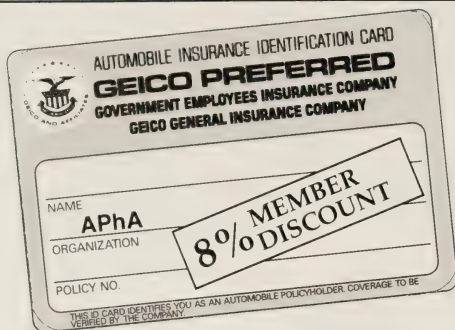
In those patients with known life threatening intolerance or allergy to TMP-SMX, aerosolized pentamidine is the agent of choice for prophylaxis and has been proven effective for both primary and secondary PCP prophylaxis. The rationale behind its use is to deliver the drug directly to the site of infection thereby avoiding systemic toxicities. Adverse effects associated with the use of aerosolized pentamidine include an unpleasant taste in almost all patients, as well as, coughing and wheezing in approximately 20-35% of patients which can usually be minimized with the use of an aerosolized beta-agonist. Discontinuation of therapy is rarely warranted.<sup>4,9</sup>

In addition to the adverse effects associated with

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**September 1993**

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aerosolized pentamidine, other concerns with using this method of treatment are notable as well. Potential exists for contaminating the surrounding environment with pentamidine and any infectious organisms that may be present in the patient's sputum. Another significant concern is the risk that patients may cough *Mycobacterium tuberculosis* into the environment thereby potentially infecting health care workers and other patients. Because of this possibility, patients should be evaluated for symptoms suggestive of tuberculosis prior to pentamidine therapy, as well as, prior to subsequent treatments. Ideally, aerosolized pentamidine treatments should take place in a room or booth with negative pressure relative to the adjacent areas.<sup>5</sup>

### Value of Prophylaxis

The Dutch AIDS Treatment Group conducted a study comparing aerosolized pentamidine to TMP-SMX as primary prophylaxis against PCP. Two hundred fifteen patients with HIV, no history of PCP, and CD4 counts < 200 per cubic millimeter were included. Patients were randomly assigned to receive one of three regimens which included: aerosolized pentamidine once a month, TMP-SMX single strength once daily, or TMP-SMX double

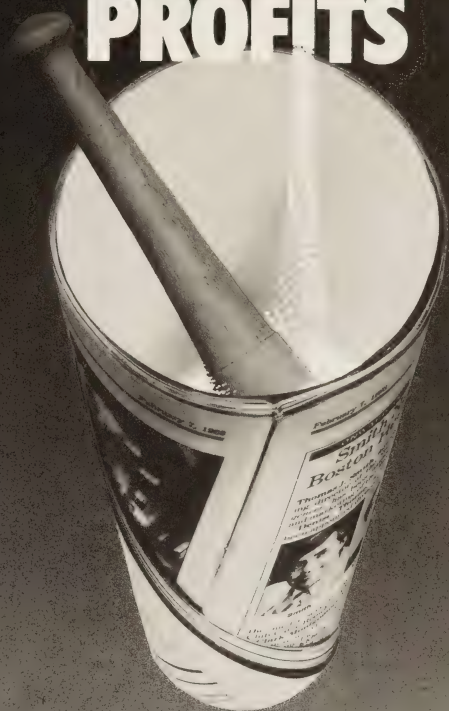
strength once daily. This study clearly showed that TMP-SMX was superior to aerosolized pentamidine against PCP, but also had a higher incidence of adverse effects. The incidence of adverse effects did not differ significantly between the two groups receiving TMP-SMX, however, the adverse effects occurred sooner with the higher doses.<sup>2</sup>

The AIDS Clinical Trial Group Protocol 021 conducted a study which compared 310 adults with AIDS who had recently recovered from an episode of PCP and had no treatment limiting toxic effects from either pentamidine or TMP-SMX. All patients were treated with zidovudine and were randomized to receive either TMP-SMX double strength daily or aerosolized pentamidine 300mg every month via jet nebulizer. This study revealed that patients treated with zidovudine and TMP-SMX had fewer recurrences of PCP than those treated with zidovudine and aerosolized pentamidine.

In a recently published study, dapsone in combination with pyrimethamine was compared to aerosolized pentamidine as primary prophylaxis against *P. carinii* pneumonia and toxoplasmosis. Dapsone 50mg was given on a daily basis while pyrimethamine 50mg was administered weekly. A standard dose of 300mg of aerosolized pentamidine was administered monthly. Data from this study

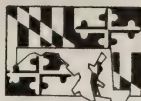


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showed the combination of dapsone and pyrimethamine is as effective as aerosolized pentamidine for PCP prophylaxis, however, it is not as well tolerated. Although the combination of dapsone with pyrimethamine allowed the daily dosage of dapsone to be reduced, several cases of hemolytic anemia were nevertheless observed. Despite these adverse effects, the combination of dapsone and pyrimethamine appears to be an attractive alternative. There were a number of disadvantages associated with the aerosolized pentamidine including treatment failures, localization of the pneumonia to the upper lungs, disseminated pneumonia, and dissemination of respiratory pathogens.<sup>13</sup> In addition, a possible drug-drug interaction with the commonly prescribed anti-retroviral, didanosine (Videx<sup>R</sup>, DDI). Dapsone is acid-labile and requires an acidic environment for absorption. Didanosine is formulated with a citrate-phosphate buffer which may inhibit the dissolution and/or absorption of dapsone. Alternatively, didanosine may increase the hepatic metabolism of dapsone. Until further trials evaluating this interaction are conducted, it is warranted that dapsone be administered 2-3 hours prior to didanosine.<sup>14</sup>

Based on this data, the United States Public Health Service Task Force on antipneumocystis prophylaxis recommends oral TMP-SMX as the preferred agent for primary and secondary prophylaxis against PCP in HIV infected patients. A study comparing dapsone-pyrimethamine and TMP-SMX is needed to determine which regimen has the best risk versus benefit ratio. Atovaquone has been compared to TMP-SMX in the treatment of *P. carinii* pneumonia, however, to date, there have been no studies of atovaquone for prophylaxis. At this time, aerosolized pentamidine remains a proven though less effective alternative prophylactic regimen for those who cannot tolerate or are allergic to TMP-SMX.<sup>3,11,13,15</sup> **R**

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## Looking to the Future

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perhaps group and family) psychotherapy, and nutritional counseling. In addition, any of the above treatment modalities may be incorporated into individual treatment plan, as indicated. The duration of treatment is highly individualized and based upon progress in therapy as well as weight gain or resolution of binge-purge behavior/control. If an individual is admitted due to an acute psychiatric difficulty, the nature of the difficulty dictates the treatment approach.

Periodically, individuals may be admitted to a general medical ward for the correction of metabolic abnormalities. These admissions tend to be brief and are usually managed by the general physician rather than the psychiatrist.

A successful inpatient treatment program includes careful planning of outpatient treatment. Prior to discharge, arrangements for outpatient treatment should be made to promote the continued progress of the individual.

### Conclusions

This is a brief overview of the treatment modalities available. Early detection of the disorder is important, but treatment may begin at anytime. Successful treatment involves not only a motivated client, but also an experienced therapist who has good therapeutic skills plus specialized training in the treatment of eating disorders. Finally, a successful treatment program is highly individualized, comprehensive in nature and should combine a variety of interventions and treatment modalities. **R**

This article and the accompanying charts were reprinted with the permission of the National Anorexic Aid Society, an educational outreach of Harding Outpatient Services. Treatment referral for inpatient and outpatient can be formed through the NAAS information hot line at (614) 436-1112. To obtain more information on eating disorders, write NAAS

at 1925 East Dublin Granville Road, Columbus, Ohio 43229.

### About The Authors

This overview was written by Amy Baker Dennis, M.A., L.P.C.C. and Randy Sansone, M.D.

Amy Baker Dennis is a psychotherapist in private practice at Midwestern Educational Resources Center, Inc., in Detroit Michigan. Ms. Dennis is the former Executive Director and founder of the Center for the Treatment of Eating Disorders. She is also the former Executive Director of the National Anorexic Aid Society. Presently, she serves as Consultant to both programs.

Randy Sansone is the Director of Psychiatry at Laureate Psychiatric Clinic and Hospital in Tulsa, Oklahoma.

Both authors have published extensively in the field of eating disorders.

"Guidelines for Approaching a Person with an Eating Disorder," "Eating Disorder Warning Signs," and "Introduction to the National Anorexic Aid Society of Harding Hospital." Reprinted by permission. In *Eating Disorders Information Packet*, The National Anorexic Aid Society of Harding Hospital, Columbus, Ohio, 1991.

For more information on eating disorders, call, FAX, or write the National Anorexic Aid Society, 1925 East Dublin/Granville Road, Columbus, Ohio 43229. Phone (614) 436-1112 or FAX (614) 848-5460.

### *Possible Signs and Symptoms Accompanying Weight Loss in Eating Disorders*

- Thinning and dryness of hair
- Lowered total sleep time
- Mildly altered thyroid function
- Pituitary hormone abnormalities
- Cold sensitivity, lowered body temperatures
- Light-headedness
- Lowered amplitude of tracing on EKG
- Fine, raised white hair on body surface (lanugo)
- Absence of menstrual periods (amenorrhea)
- Brittle nails
- Loss of subcutaneous body fat
- Lowered reflexes
- Mild fluid collection (edema)
- Dry skin
- Diminished muscle mass
- Mild anemia
- Constipation
- Slowed heart rate
- Lowered heart size on chest x-ray (loss of fat pad around heart)



# Approaching a Person with an Eating Disorder

Pharmacists are in a unique position for identifying patients at risk for eating disorders. Whether it be through repeated purchases of laxatives, diuretics, diet pills, or syrup of ipecac, a pattern of signs may not be seen by another health professional other than the pharmacist. If you think a patient, or even a family member may have an eating disorder, this list of guidelines was developed by the National Anorexic Aid Society to help approach a person with a suspected eating disorder.

## General Guidelines

- Recognize your own attitude and amount of focus on your weight, body shape, and dieting practices. How might this be triggering or encouraging a friend, family member or child to follow your pattern?
- Try not to use food as a socializing agent.
- Recognize that food has a purpose: to fulfill hunger.
- If there are family or friendship disagreements, try not to argue at the table. Such negative experiences become associated with eating and then food is thought of as a problem.
- Allow the eating disordered person to be in charge of their own eating.
- Avoid monitoring the food that the person eats, once the person is in treatment.

## Guidelines for Family Members and Friends

- Do not treat the person with an eating disorder like a child. If you are a parent, do not deny your daughter or son some parental guidance, but at the same time remember that he/she has many adult abilities which need to develop.
- When you speak to the person, speak with compassion and concern. Be as descriptive as possible.
- Avoid focusing on how the person looks with comments such as: "You're looking far too thin." or "You're looking great!" This encourages body image obsessions. Instead focus on other areas of the person's life as much as possible.
- Explain what you suspect by describing the person's problematic behaviors. State your observations.

*Example 1* "I'm noticing that you are skipping meals. You're eating less at each meal. You're exercising more and it's obvious that you are losing a large amount of weight. I'm concerned for your health."

*Example 2* "I'm noticing that whenever I buy candy bars or cookies, they suddenly disappear. When I ask you about them you say you don't know anything about it. Yet I have found the wrappers laying around. It seems that you are eating all the food."

- Negotiate acceptable behavior with the person. For example: If the person is eating your food, clarify with the person that he/she will be charge for it.
- Do not allow the dysfunctional behavior to be overlooked, otherwise, you are rewarding it. You need to increase the person's responsibility for his/her behavior.
- Set rules with the person regarding what is acceptable food to eat and how many meals a day are acceptable. Then focus conversation on other topics.

---

*People with eating disorders are extremely sensitive to the opinions of others. They feel insecure and inadequate.*

---

- If a person is binge eating, discuss with the person how you could help him/her. For example: Perhaps they may want you to remove binge foods from obvious places to discourage binge eating.
- Do not use scare tactics. They are not appropriate and they do not work.
- Give the person time to improve unless you suspect that his/her life is in danger. Negotiate a plan that may include certain behaviors such as eating regularly or decreasing purging. If the verbal contract is broken, seek professional help.
- If a person appears to be showing signs of extreme physical problems, yet refuses help, a decision needs to be made by the parents and professionals to determine if treatment is necessary and how to initiate it.
- Try not to spy or interfere once the person with an eating disorder is in treatment.
- Provide specific information for help, names of treatment providers and phone numbers. There may be eating disorder specialists in your community or there may be support groups for eating disorders. Have the information available when you approach the person.

### Don't Forget

- The person with an eating disorder is sensitive to non-verbal behavior judging others' attitudes toward them by a fleeting expression, a tone of voice, or even the movement of your body.
- Try to remember their intense feelings of inadequacy. Attitudes of scorn, disgust, or impatience exhibited toward a person with an eating disorder intensifies his/her symptoms.
- Recognize that the person may deny your observations and be upset (especially if anorexic). Try not to be discouraged. Recognize that you have broken through his/her psychological defense. The person is frightened.
- Do not expect an immediate 100% recovery. As with any disorder, there will be a period of convalescence. There may be relapses. There will be difficult days when all of the old tensions flare up again.

R

### On the Corner

Frank McGinity, P.D.

According to Maryland law, prescribers must write prescriptions legibly. The potential for mistakes from illegible writing is serious. While you're reading the answers to last month's mystery prescriptions, think of some unusual prescriptions you've seen lately and send them to "On the Corner," MPhA, 650 West Lombard Street, Baltimore, MD 21201, FAX (410) 727-2253.

#### Answer to July Prescription #1

Larotid 200mg, #14, Sig: 1 BID

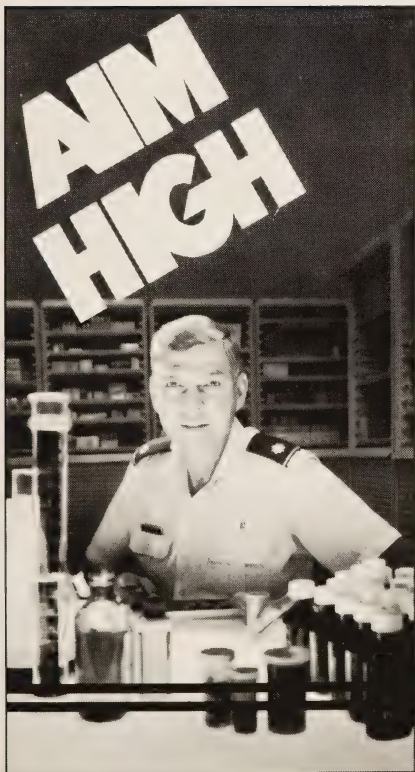
#### Answer to July Prescription #2

Vivactyl 10mg, #20, Sig: tab i TID  
Refill #100 (prn refills)

#### Answer to July Prescription #3

Keflex 500mg, PO i 4 daily

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- the clinical impact on patient outcomes
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# Courts To Hear "Reliable" and "Relevant" Science

David B. Brushwood, J.D.



The much awaited "junk science" case has been decided by the Supreme Court of the United States. This case considered whether juries should be permitted to hear the testimony of anyone professing to have a scientific basis for testimony, or whether judges should permit juries to hear only those whose testimony is generally accepted in the scientific community.

The case that brought this issue to the court's attention was a Bendectin case, in which the overwhelming weight of the generally accepted scientific evidence failed to demonstrate a causal relationship between the drug and birth defects. For this reason, most judges had dismissed Bendectin cases, ruling that juries should not be permitted to reach emotional verdicts based on something other than science. However, the plaintiff in this Bendectin case offered the testimony of several experts, all of whom claimed that Bendectin causes birth defects, but none of whom based their testimony on generally accepted science.

The issue in cases such as this is whether juries should be permitted to sift through scientific evidence, on the other hand, judges similarly lack scientific expertise, and if the evidence is really invalid, then juries can perhaps be instructed on how to recognize that.

The Supreme Court reversed the lower court that had dismissed the case against the manufacturer. The lower court had ruled that only peer-reviewed published scientific data can serve as the basis for scientific testimony relating to epidemiology. While the Supreme Court disagreed with that approach, which supported the position that only generally accepted science should be produced as evidence in courts, the Supreme Court did place a restriction on the authority of judges to permit juries to hear scientific testimony. Judges must now, under this opinion, weigh the evidence and make sure that a scientific expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Judges must make a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly can be applied to the facts at issue. For the time being, the plaintiff has won this appeal, but it is entirely possible that the offered evidence will fail this new standard for admissibility, and the plaintiff will end up losing after all.

R

Based on: *Daubert v. Merrell Dow Pharmaceutical*, 1993 Westlaw 224478 (U.S. 1993)

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# Continuing Education

## Continuing Education Quiz

August 1993 -- Eating Disorders

This month's questions are taken from the articles on eating disorders that appear in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by January 31, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

1. Anorexia nervosa is an eating disorder which occurs in an estimated:
  - a. 1% of the general population
  - b. 1% of the adolescent population
  - c. 10% of the general population
  - d. 10% of the adolescent population
2. Symptoms of anorexia nervosa include:
  - a. behavioral changes
  - b. ritualistic behaviors around eating such as exact food placement on the plate.
  - c. mood changes
  - d. all of the above
3. Complications of anorexia nervosa due to starvation include:
  - a. obesity
  - b. reduced energy
  - c. slowed heart rate
  - d. increased thyroid functions
4. Bulimia nervosa is characterized by:
  - a. binge eating
  - b. eating hypocaloric foods
  - c. excessive laxative and/or diurectic use
  - d. both a and c
5. It is uncommon for individuals with anorexia nervosa to develop bulimia as well.
  - a. true
  - b. false
6. Common purging tactics for bulimia include:
  - a. rigorous dieting and exercise
  - b. self-induced vomiting
  - c. laxative abuse
  - d. all of the above
7. Causes of eating disorders can be linked to:
  - a. a single event in the patient's life
  - b. one causative factor
  - c. multiple factors including genetics, biological, psychological, personality, sociocultural and familial factors.
  - d. none of the above
8. Laxative abuse is characterized by:
  - a. overactive bowel functioning
  - b. non-specific bowel complaints
  - c. enhanced absorption of fat, protein, and calcium
  - d. none of the above
9. Possible medical complications of weight loss methods which are most dangerous involve:
  - a. effects on potassium regulation and fluid balance
  - b. cathartic colon
  - c. non-specific abdominal complaints
  - d. hair loss
10. Treatment with antidepressants in individuals with eating disorders must consider the following issues:
  - a. the type of depression
  - b. the metabolic state of the individual
  - c. enhanced sensitivity to side effects in individuals who are severely starved or malnourished.
  - d. all of the above

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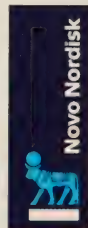
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NO. 9



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*Preparing for  
"Talk About Prescriptions" Month*



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## President's Commentary

*Howard Schiff, P.D.*



In the community setting talking about prescriptions is often a difficult task at best. The phones are ringing, the scripts are piling up, the morning coffee is starting to work on you, the tech is off today, the boss is interested in production, not commentary, and the questions patients most often ask are "How long?" and "How much?".

That may be the way we practice today, but there is no assurance that we'll be able to practice that way tomorrow. With automation rapidly changing many of the tasks pharmacists have traditionally performed and state and national health care reform threatening to do away with those routine tasks, the surviving pharmacist will be the confidant of the patient, the professional in the loop with other health care providers. He or she may well be the most personal contact the patient has in an increasingly impersonal health care system. Now is the time to take the time to show your concern for the patient and your knowledge of their drug therapy because to delay might hinder your profession and your ability to make a satisfactory income in the years ahead.

Changes are in the offing, but they won't come overnight. They'll come only with a gradual public acceptance of our expanded informational role. For graduates of the 50's, 60's and early 70's who were taught *not* to talk to patients, this is particularly difficult. No one ever expected us to know how to "win friends and influence people." The demands of the market place still do not require it. The demands for survival of the profession in the community setting do. It is only with our demonstration of the ability to talk about prescriptions, or to use its proper name, perform pharmaceutical care, that we can positively affect patient therapy outcomes and reduce the overall cost of health care. For this service we can demand payment unrelated to the product we dispense. Now that is a service that can be expected of a professional with our expertise and education.

**R**

## Guest President's Commentary

Kathrin Kucharski, Pharm.D., President, Maryland Society of Hospital Pharmacists



**The Scene:** Your pharmacy school graduation party. Your friends and family are gathered to celebrate.

**Grandma:** "So now that you've finished all these years of school, where are you going to work?"

**Graduate:** "I'm going to work in hospital pharmacy."

**Grandma:** "Are there pharmacies in hospitals? I guess I've seen one where patients get prescriptions filled after going to clinic."

**Friend:** "Is the hospital pharmacy the little place in the basement with the bars in the window where I've picked you up on Friday nights?"

**Uncle:** "What do you do in a hospital pharmacy? When I had my heart attack, all of the medications came prepackaged. What else is there to do?"

**Graduate:** "Well, I do a lot of other things. I am responsible that the right medications is prepared for all of the patients, I check for drug interactions, I prepare a lot of the IV medications, etc. etc. etc. and every day I round with the critical care team and provide recommendations regarding medication therapy."

**Friend:** "You actually get out of that little room in the basement?"

Does this scene sound all too familiar? Many patients are not aware that pharmacists even exist in institutional settings let alone what services we provide and how those services can be integrated with those of other health professionals. Institutional pharmacists have not done a great job in educating the public about what we do. In the era of health care reform, the institutional pharmacist is going to play a key and pivotal role in providing pharmaceutical care. We can be the link between the institutional and outpatient settings. We have the advantage of having access to the patients' medical records as well as the outpatient history. We have a "captive audience" when it comes to providing medication information (i.e. discharge counseling) and teaching. We are the ones who can intervene when a patient is admitted due to an adverse drug reaction.

The patient needs to be aware of the services we already provide and what services are available to them. October is "Talk About Prescriptions Month" with the theme of "Let's Talk". Please take this opportunity to broadcast what an institutional pharmacist does. There is an ASHP video titled "The Invisible Ingredient" directed towards lay people available on loan from MSHP. Use this video or any other material (especially that available in the this month's issue of *The Maryland Pharmacist*) to provide a lobby or cafeteria display. Other activities could include educational sessions for volunteers, a brown bag program during lunch, or medication discharge counseling. Most of all, be visible and available to our patients. **R**





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pharmacies  
belong to  
Valu-Rite.  
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be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."



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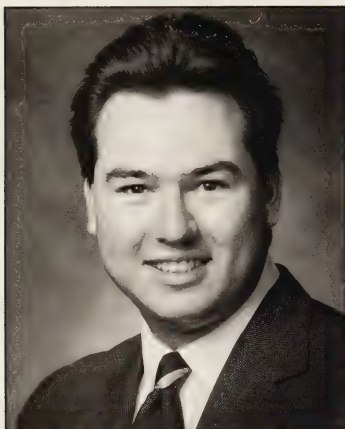
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# Maryland's Health Care Reform Initiative

## *What it Says and How it Impacts Pharmacy*

*David G. Miller, P.D., Executive Director*



This past April, Governor Schaefer signed into law one of the first comprehensive state health care initiatives. Hailed by many as a major step forward in reforming the state's troubled health care system, a system that cannot be accessed by more an estimated\* 650,000 uninsured Marylanders, House Bill 1359 (HB 1359) is also looked at as a model for the Clinton Administration's reform proposals.

Almost six months later, many still don't fully understand the complexity of this legislation. However, it is clear what this reform initiative is not. It is not a universal health care plan and it does not guarantee coverage for the currently uninsured. It is not a single payor system. It is not a requirement for employers to provide health care insurance for employees. It does not dramatically change the way health care is delivered or paid for in Maryland.

HB 1359 is an amalgam of three different types of legislation: small employer group insurance market reform, establishment of an oversight commission to review health services and costs, and a reform of the general health insurance market.

### **Small Employer Group**

The biggest barrier to providing health insurance is cost. In no other group has this been more of an issue than for small employers who want to provide health insurance but simply can't afford it. An integral part of HB 1359 is Sections 698 through 713 of new Subtitle 55 (Health Insurance Reform) under the Insurance Article

of the Maryland Annotated Code. These sections make a series of changes in health insurance practices designed to protect and enhance access to health insurance for small employers and either slow or stabilize the dramatic increases in health insurance premiums. These changes go into effect July 1, 1994 for all insurers and carriers selling health insurance to the small employer group market.

HB 1359 defines a small employer as: "any person, sole proprietor, firm, corporation, partnership, or association actively engaged in business and on at least 50 percent of its working days during the preceding calendar year employed at least two but no more than 50 eligible employees, the majority of whom are employed within the state. Until January 1, 1995 carriers who do not impose preexisting conditions limitations may require that a small employer have at least three eligible employees." Eligible employees are defined as employees who work a normal work week of 30 or more hours. Eligible employees are not independent contractors, temporary employees, part-time employees who work fewer than 30 hours per week, or employees with health insurance coverage from a public or non-employer private source.

All health insurers doing business with small employers must comply with the HB 1359's changes. Similarly, small employers who meet the above definitions may only purchase their health coverage from an insurer or carrier who meets and complies with the new law. The law does not



affect large employers; however, depending on a Federal waiver of ERISA (Employee Retirement and Income Security Act), large employers may eventually have to play by the rules set down by HB 1359.

### Insurer Requirements

Small employers will receive many protections under HB 1359. These protections are designed to correct many of the problems small employers have faced from health insurers -- policy cancellations, employee exclusions, pre-existing conditions, denied coverage, and high premiums.

**Guarantee Issue** Carriers must issue a health benefit plan -- either an insurance plan or an HMO plan -- to any small employer as long as the employer requests coverage, meets the definition of "small," pays the premium, and satisfies other requirements set forth by Maryland's Insurance Commissioner. A carrier may require a minimum participation of eligible small employers. A carrier may not require minimum employer contributions for payment of premiums.

**Guarantee Renewal** Carriers must renew a health benefit plan and cannot exclude any eligible employee or dependent from coverage. Cancellation can only occur for the following actions by the small employer: non-payment of premium, fraud or misrepresentation, noncompliance with provisions approved by Insurance Commissioner, and repeated misuse as defined by the Insurance Commissioner. The carrier

can also cancel coverage as long as six months notice is given to *all* small employers (the carrier is getting out of the small employer group market business) or if the Insurance Commissioner finds that the carrier is not able to meet its contractual obligations with small employer groups.

**General Protection** Carriers must make disclosures in their solicitation and sales material regarding provisions covering: changes in premiums, renewals, and pre-existing conditions.

**Pre-Existing Conditions** Beginning January 1, 1995, carriers will be prohibited from excluding employees or their dependents for pre-existing conditions. This provision alone will protect many Marylanders. HB 1359 defines pre-existing conditions as a medical or health condition that would cause a reasonable person to obtain care or for which care was recommended (e.g. hypertension, diabetes). A pre-existing condition exclusion cannot be imposed for any services related to pregnancy or newborns. After January 1, 1995, a late enrollee -- a person not requesting enrollment after 30 days becoming an eligible employee -- may be subject to a 12 months pre-existing condition. A health benefit plan not using a pre-existing condition may require a 30 day waiting period for enrollees before coverage is effective.

**Portability** One of employees' greatest fears is that if they leave their job, they will lose their health insurance. HB 1359 provides that coverage must continue, as long as

premiums are paid, even if an employee leaves their employer. This provision, however, is good only for six months. Within that time, the employee must obtain employment with an insuring employer or the health insurance carrier may require higher deductibles or other cost-sharing.

**Adjusted Community Rating** HB 1359 provides for an adjusted community rating system as opposed to a pure community rating system. A community rating system is one in which everyone pays the same premium, regardless of demographics or health conditions. The adjusted community rating is two step process. The carrier determines a rate or premium based on the entire pool of risks covered by a benefit plan without regard to health status or occupation. Second, the carrier then may adjust this community rate for age, family composition, and geography based on specific geographic areas set forth in the law. Simply put, this helps make sure that a Cumberland pharmacy in Western Maryland employer is not subsidizing an Ocean City pharmacy on the Eastern Shore. The concept of community rating is to smooth out the differences in rates. Community rating, by itself, is not designed to reduce rates, but to stabilize future rate increases.

### The Commission

Another major portion of Maryland's health reform plan is the establishment of the Health Care Access and Cost Commission

(HCACC). This Commission is composed of seven individuals appointed by the Governor, four of whom may not have any connection with the management or policy of a health care provider or payor. HCACC is an independent agency with wide ranging powers as well as general authority over the implementation of HB 1359. The Commission will have a \$5 million annual budget funded through a insurers and providers. The provider community is responsible for paying 1/3 of the \$5 million through an additional fee attached to the professional license issued by the Department of Health and Mental Hygiene. At this point, however, *pharmacy and pharmacists are the only provider group who are specifically excluded from having to help fund the Commission's budget.* This exclusion is the direct result of efforts by the Maryland Pharmacists Association during the crafting of HB 1359. It was MPhA's belief, a belief shared by

legislators, that since pharmacists are already far enough advanced in technology and other reform requirements to be set forth by the HCACC it would be unfair for us to share the costs of bringing other provider group up to speed. Think of this as the "adjusted community rating" described above except applied to the fees paid by the provider community.

The HCACC is charged with several major tasks: development of a comprehensive standard benefit package, establishment of a medical care data base, creation of cost containment strategies, and oversight of the health care payment system including annual adjustment goals.

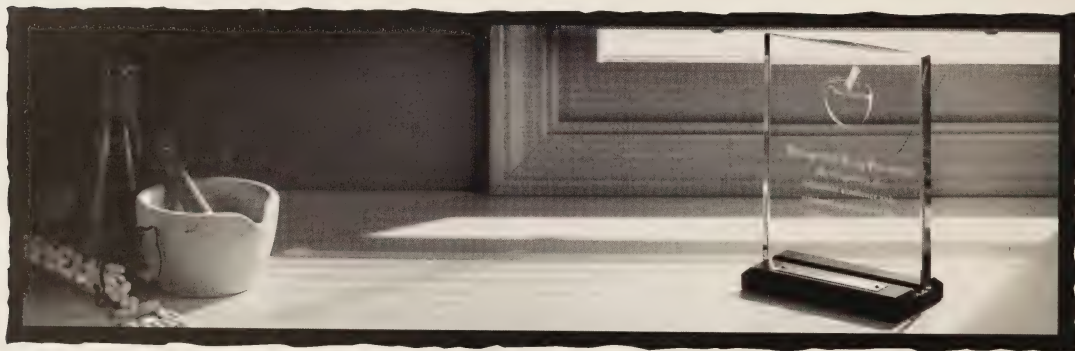
#### Standard Benefits Package

The HCACC is charged with developing a Comprehensive Standards Benefit Plan (Plan). Initially, this plan must be the *minimum* coverage offered by carriers

to the small employer group market. As with other insurance reform provisions, this plan could eventually expand into the general insurance market for large employers. At this point, a pharmacy benefit is part of the standard benefits plan being prepared by the Health Care Access and Cost Commission.

The Plan may exclude any of Maryland's existing legally mandated benefits. HB 1359 sets as a minimum for the Plan the "actuarial equivalent" of the benefits required to be offered by federally qualified HMO's. The plan must have uniform deductibles and cost sharing (copayments). The maximum annual premium, averaged across a carrier's community rating population, for this basic plan may not exceed 12% of the annual average wage in Maryland. The HCACC can adjust the Plan annually to meet the 12% ceiling by changes in benefits, deductibles or co-pays.

*Continued on page 23....*



**This award recognizes a pharmacist who has done more than provide quality service. She's improved the quality of life.**

For a young professional, it's one of the more prestigious honors that can be received - ask Kathrin Kucharski, Marion Merrell Dow's 1993 "Distinguished Young Pharmacist" Award winner in the state of Maryland.

Every year, our award recognizes one pharmacy professional in each state who goes above and beyond the call of duty.

In quality of service, in community and pharmacy association activities, and in working to improve the quality of life for customers. One who's leading the profession toward better health care tomorrow.

Our award winners are more than very good pharmacists. They're very good human beings. To us, that's the highest honor of all.



Your prescription for better business.™

# *Special Pull-Out Section*



## *Let's Talk<sub>x</sub>*

*Materials for  
"Talk About Prescriptions" Month and  
National Pharmacy Week*



## List of Prescription and Non-Prescription Medicines I Am Taking

### GET THE ANSWERS

Remember to ask your doctor, pharmacist, or other health care provider:

- 1** What is the name of the drug and what is it supposed to do?
- 2** How and when do I take it – and for how long?
- 3** What foods, drinks, other medicines, or activities should I avoid while taking this drug?
- 4** Are there any side effects, and what do I do if they occur?
- 5** Is there any written information available about the drug?

### Personal Medical Data

My blood type is \_\_\_\_\_

I am allergic to: (please check)

- ☐ Codeine ☐ Morphine ☐ Penicillin ☐ Insect Bites
- ☐ IVP Dye ☐ Other \_\_\_\_\_

My medical condition includes:

- ☐ Arthritis ☐ Heart Condition ☐ Contact Lenses ☐ Hypertension
- ☐ Emphysema ☐ Pacemaker ☐ Diabetes ☐ Hearing Aid
- ☐ Glaucoma ☐ Hemodialysis ☐ Epilepsy ☐ Anti-coagulants
- ☐ Abnormal ☐ Removable Dentures ☐ Other \_\_\_\_\_

EKG \_\_\_\_\_

Doctor's Name \_\_\_\_\_

Phone Number \_\_\_\_\_

My Patient Chart Number is \_\_\_\_\_

### Notify in Emergency

Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

## Lista de medicinas que estoy tomando

(con o sin receta médica)

### OBTENGA LAS RESPUESTAS

Recuerde preguntar a su médico, farmacéutico, u otro proveedor de servicio de salud sobre sus medicinas

- 1** ¿Cuál es el nombre de la medicina y cuál es su efecto indicado?
- 2** ¿Cómo y cuándo debo tomar la medicina y por cuánto tiempo?
- 3** ¿Qué alimentos, bebidas, y otras medicinas o actividades debo evitar mientras estoy tomando la medicina?
- 4** ¿Hay algunos efectos secundarios, relacionados con la medicina y que debo hacer si estos efectos ocurren?
- 5** Hay información escrita disponible sobre la medicina?

### Información Personal Médica

Nombre \_\_\_\_\_

Mi tipo de sangre es \_\_\_\_\_

Soy alérgico a: (favor de marcar)

- ☐ Codeína ☐ Morfina ☐ Penicilina
- ☐ Picadas de insectos ☐ Solución de contraste intravenosa para urograma descendente (IVP-Dye)
- ☐ Otros \_\_\_\_\_

Mi condición médica incluye:

- ☐ Artritis ☐ Condición del corazón ☐ Hipertensión
- ☐ Emfisema ☐ Lentes de contacto ☐ Marcapaso
- ☐ Glaucoma ☐ Aparato Auditivo ☐ Dentaduras removibles
- ☐ Epilepsia ☐ Hemodálisis ☐ Anticoagulantes
- ☐ Diabetes ☐ Electrocardiograma anormal ☐ Otros \_\_\_\_\_

Nombre del médico \_\_\_\_\_

Número de teléfono \_\_\_\_\_

Número de mi récord de paciente \_\_\_\_\_

### En caso de emergencia notifique a:

Nombre \_\_\_\_\_

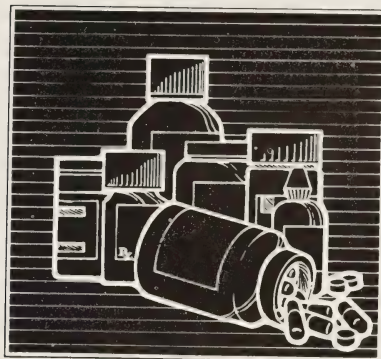
Dirección \_\_\_\_\_

Teléfono \_\_\_\_\_

---

GET  
THE ANSWERS

---



---

Remember, the more  
you know about the  
medicines you take,  
the better they  
will help take care  
of you. But, . . .

---

---

... you have to ask questions.

---

Every day, millions of Americans rely on prescription medicines to feel better and get well. But studies show that up to 50% of prescription drugs are not taken properly.

If you don't take your drugs at the right times or for long enough, you might not get well as fast as you could.

Taking them with certain foods or other drugs might give you a bad reaction. Or it might stop your medicine from working as well as it could.

Asking the following five questions is a good start. But don't stop there. Keep working with your health care practitioners. They are partners in your drug treatment. They want to help you use your medicines properly.

**1**

What is the name of the drug and what is it supposed to do?

**2**

How and when do I take it — and for how long?

**3**

What foods, drinks, other medicines, or activities should I avoid while taking this drug?

**4**

Are there any side effects, and what do I do if they occur?

**5**

Is there any written information available about the drug?



## Five Factors Determine How Alcohol Affects You and Your Medicines.

- What medicine or medicines you take.
- The amount of the medicine you take.
- How much alcohol you drink.
- When you take the alcohol and when you take the medicine.
- How your body processes (metabolizes) medicines.

## Be Safe: Ask Your Health Professionals

**TALK** to your doctor, pharmacist or nurse if you take a prescription, or plan to take medicine such as aspirin or allergy medicines.

**ASK.** Should you avoid alcohol — or any foods, other beverages such as coffee or caffeinated soft drinks, other medicines?

**GET SPECIFICS.** Find out what could happen if you mix medicines and these substances.

**LEARN** how you can reduce risks and avoid dangerous effects.

**PLAN** for special occasions or other times when you'd normally drink alcohol or use these other substances.

Don't skip doses of your prescribed medicine. Don't change your schedule or stop taking a medicine without consulting your health care professional.

With expert advice, you can avoid harmful interactions and enjoy all the benefits your medicines have to offer.

This brochure was made possible in part by a grant from the Licensed Beverage Information Council. The content is entirely the responsibility of NCPIE.

✶ ✶ **National Council on Patient Information and Education**  
✶ ✶ 666 Eleventh Street, NW, Suite 810  
Washington, DC 20001

NCPIE encourages professionals and community groups to foster patient-professional communication about medicines. However, NCPIE does not supervise or endorse the activities of any group or professional. Discussion and action concerning medicines are solely the responsibility of the patient and their health care professionals, and not NCPIE.

**Alcohol  
and  
Medicines:  
Ask  
Before  
You Mix**

**Prescription and nonprescription medicines can help you stay healthy if taken correctly.**

**Taking medicines right requires understanding what foods, beverages and other medicines can prevent a prescription from working properly.**

**Common substances such as caffeine, tobacco, dairy products and alcohol can affect how a medicine works.**

**This brochure looks at one of these: **ALCOHOL****

## **Alcohol and Medicines:**

About 100 prescription medicines can produce unwanted effects when mixed with alcohol.

Alcohol can interact harmfully with some common nonprescription medicines such as aspirin and allergy medicines.

When alcohol and some medicines are mixed the problems can be minor or very severe. It can even be fatal.

It's important to understand when, if and how alcohol and medicines can be mixed.

## **What Can Happen:**

Here are a few examples of alcohol-medicine interactions\*

<b>Mixing Alcohol with:</b>	<b>Can Cause:</b>
<b>Analgesic Pain Medication</b> <ul style="list-style-type: none"><li>• Salicylates (aspirin, such as Bayer, Empirin)</li><li>• Ibuprofen (such as Advil, Motrin)</li></ul>	Stomach and intestinal bleeding, bleeding ulcers
<b>Antidiabetic Agents</b> <ul style="list-style-type: none"><li>• Chlorpropamide (such as Diabinese)</li><li>• Tolbutamide (such as Orinase)</li><li>• Insulin (such as Humulin 70/30)</li></ul>	Altered control of blood sugar, most often hypoglycemia
<b>Barbiturates</b> <ul style="list-style-type: none"><li>• Secobarbital (such as Seconal)</li><li>• Phenobarbital (such as Barbital)</li><li>• Pentobarbital (such as Nembutal)</li></ul>	Greater sedative effect, drowsiness, confusion
<b>Benzodiazepines</b> <ul style="list-style-type: none"><li>• Alprazolam (such as Xanax)</li><li>• Diazepam (such as Valium)</li><li>• Triazolam (such as Halcion)</li></ul>	Greater sedative effect, impaired motor coordination (such as driving ability)
<b>Monoamine Oxidase (MAO) Inhibitors</b> <ul style="list-style-type: none"><li>• Isocarboxazid (such as Marplan)</li><li>• Phenelzine (such as Nardil)</li><li>• Tranylcypromine (such as Parnate)</li></ul>	Certain alcoholic beverages contain tyramine that can cause severe high blood pressure that may be fatal

\*This selected listing of medicines by chemical and brand name is only intended to provide examples. The risks cited do not always occur, but be safe, ask your health care professionals whether any of the medicines you take can interact with alcohol.

## **Alcohol, You and Your Medicines**

- Alcohol makes some medicines work less effectively. You don't get their full benefit.
- Sometimes alcohol increases the effects and the risks of a medicine to potentially dangerous levels.

# Your Right To Know About Prescriptions

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BALTIMORE COUNTY

## IV. THE RESPONSIBILITY OF THE PUBLIC IS:

### TO KNOW THE CONSEQUENCES OF FILLING OR WRITING A FORGED PRESCRIPTION

### TO KNOW THE CONSEQUENCES OF ALTERING PRESCRIPTIONS

### TO KNOW THE CONSEQUENCES OF PASSING MEDICATIONS/ PRESCRIPTIONS ON TO PERSONS OTHER THAN THOSE NAMED ON A PRESCRIPTION

## V. WHERE TO GET FURTHER INFORMATION

- Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, Maryland 21215
- United States Pharmacopeia—  
Advice for the Patient  
Copyright—US Pharmacopeial  
Convention, Inc., 1992  
12601 Twinbrook Parkway  
Rockville, Maryland 20852
- Maryland Pharmacy Act  
Board of Pharmacy Regulations and  
Drug-Related Statutes and Regulations  
Available from:  
Maryland Pharmacists Association  
650 West Lombard Street  
Baltimore, Maryland 21201

- No one, including physicians, can  
interfere with your freedom of choice  
of a pharmacy.
- It is not necessary that you buy your  
drugs from a particular pharmacy.  
However, since prepaid medical plans  
may require patients to acquire their  
prescriptions from select pharmacies,  
please become familiar with your plan.



At one time or another, most of us will find it necessary to use medications. The common perception is that these medications, whether prescribed by a health practitioner, or obtained over the counter (prescription not required), will make us feel better if not cure us entirely. In 1992 over \$20 billion was spent on prescription drugs, and another \$8 billion on non-prescription drugs. Studies show, however, that up to 50 percent of all prescriptions are taken incorrectly. Pharmacists are available for counseling and providing information about drug usage, interactions with food or other drugs, and side effects. There is a grave need for a straightforward objective guide to drugs that cautions and informs the consumer about prescription drugs as a part of medical care.

This pamphlet is designed to help consumers become aware of their rights as patients receiving medication.

## **I. HOW TO GET THE BEST PHARMACEUTICAL SERVICE AVAILABLE**

- Medication needs may vary—when and what drugs you need should dictate when and where to buy.
- Not all pharmacies are the same although the same quality is assured in so far as prescription filling is concerned.
- Some services vary from pharmacy to pharmacy such as home delivery, credit arrangements, hours of service, facsimile machines and discount prices. Choose the pharmacy that offers you the services you desire.

- Generic substitutes for trade name drugs are available in many cases upon your request. Please discuss this option with both your physician and pharmacist.

- All pharmacists have the same license to practice. Each person is responsible for the services they provide. Pick your pharmacist the same as you would your doctor, dentist or other professional.

- Ask your friends, relatives and colleagues about the pharmacies in your area. See what they like and dislike and compare that information with your needs and desires.

- Please tell your pharmacist about your drug history including allergies and any special problems you may have regarding your medications.

- Be sure you understand the label completely—do not leave the pharmacy until you know exactly what to do.

## **II. CLINICAL INFORMATION ABOUT THE DRUG(S) YOU WERE PRESCRIBED**

- Do they have any side effects that you need to inquire about?

- Are there any special cautions about their use?

- Are you at any special risk because of your family history, drug history, etc.?

- What effect might this drug therapy have on pregnant or nursing women?

- Are there significant drug interactions related to your drug regimen or diet?

- Is there a potential for this drug to be habit forming?

- Are there any special precautions necessary relating to activities such as operating machinery while taking this drug?

## **III. WHAT ELSE IS IMPORTANT BEFORE, DURING AND AFTER TREATMENT WITH MEDICATIONS**

- If you get home and realize you have forgotten or don't understand what you were told—CALL BACK AND ASK AGAIN.

- Report any changes in yourself that may be related to your medication to your doctor or pharmacist.

- Never take any one else's prescription medication.

- Insist on answers from each of your health care providers: physicians and pharmacists alike.

- You should expect prompt, courteous service—you should receive pertinent information as well as your drugs.

- Your pharmacist should show necessary concern for your drug related problems.

- Know how long your medications are good for, as well as how and when to dispose of them.

- Be aware of how to store and travel with prescription medications—this may alter their effectiveness.

- Tell each physician you see of medications you have received from other physicians.

- If you visit more than one pharmacy for drugs, be sure to tell the pharmacist about the other drugs you take.

- Ask your pharmacist if he/she maintains patient drug profiles. They may be helpful in avoiding problems with drug interactions, etc.

- According to the law, pharmacists are required to quote prescription prices over the phone.

# Medicine Record

To help you remember to give all your child's doses at the right times, fill in clock face with time of dose and check off each dose as you give it!

WEEK #1 MON. TUES. WED. THUR. FRI. SAT. SUN



WEEK #2 MON. TUES. WED. THUR. FRI. SAT. SUN



Name of Medicine \_\_\_\_\_

## A Parent's Guide For Medicine Use by Children



**Speak Up  
For Children**  
Talk About Prescriptions



National Council On Patient Information and Education  
666 11th Street, NW  
Suite 810  
Washington, DC 20001  
202/347-6711

# Speak Up For Children Talk About Prescriptions

**M**edicines can help your children feel better and stay active. Sometimes they even save lives.

To work the way they should, medicines must be used properly. When we make mistakes in the way we give medicines, children don't get well. Some mistakes cause problems that can put your child's health -- and life -- at risk. The common mistakes that hurt children's health include:

- Stopping a medicine too soon or too suddenly.
- Not giving enough of a medicine (forgetting or skipping doses and giving them at the wrong times).
- Letting a child refuse to take a medicine (or deciding on your own not to follow the doctor's advice).
- Giving too much of a medicine (giving larger doses or giving them more often than advised).

How can you be sure that you do what's best for your child? The first step is to speak up. Talk to your health professionals, your children, and the others who take care of your children about every medicine they take.

## Talk to Your Health Professionals

- Discuss the decision to begin or continue use of any medicine.
- Find out about non-drug approaches that may be used along with medicines.
- Ask your doctor to explain the benefits and the potential risks of medicines he or she prescribes for your child.
- Tell your doctor or pharmacist about other medicines your child is taking, including over-the-counter medicines. This can help prevent drug interactions.

- Ask doctors and pharmacists the 5 questions that appear on this brochure. Take the brochure along when you visit the doctor's office or pharmacy. Use the space provided to write down the answers.
- Never stop, or adjust, the dosage of your child's medicine without consulting the doctor.
- Monitor and report on your child's response to the medicine. If you think it is causing side effects, let the doctor know. Don't be afraid of "bothering" him or her. Doctors need feedback to give the best treatment.
- Call the doctor or pharmacist if you have other questions later on. Don't "guess" when it comes to medicines.

## Talk to Your Child

- Teach your children that proper use of medicines is a key to good health, just like eating right or brushing your teeth.
- Explain the difference between legitimate medicines and illegal drugs. Use only the word "medicines" to talk about prescriptions and over-the-counter medicines. Use the term "drugs" to refer to illegal substances.
- Encourage your children to ask questions of the doctor and pharmacist about the medicines they will be taking. Show them how by your example.
- Decide together which responsibilities you and your child will have in following the treatment. A younger child might help you remember each dose; a teenager might take the lead, with you monitoring and providing back up.
- Get your child's help in solving problems that make it hard to follow treatment, such as remembering medicine in a busy schedule, taking medicines in school, and coping with side effects.

## Talk to The Others Who Care For Your Children

**The Other Parent.** Both parents and step-parents should be involved in helping the child take medicine. Share information you get from the health professional. Explain instructions. Clarify the roles each of you will play.

**Grandparents, Day Care Helpers, Babysitters.** Explain the medicine schedule and treatment details to all those who give your child medicine in your absence. Follow up to be sure your instructions were carried out.

**Schools and Teachers.** Tell school personnel if your child is taking a long-term medicine or if a dose is needed during school. Involve the teacher or school nurse in watching for side effects, problems in taking medicines, or other problems.

# Get The Answers To These Questions From Your Doctor Or Pharmacist

Write The Answers In The Space Provided As A Reference For You And Others Who Care For Your Child.

1. What is the name of the medicine and what is it supposed to do?

2. How and when do I give the medicine and for how long?

3. What food, beverages, other medicines, or activities should the child avoid while taking the medicine?

4. Are there any side effects, and what do I do if they occur?

5. Is there any written information available about the medicine?



# Sample Articles

*Encourage a local newspaper or consumer health newsletter to publish one or more of these articles during National Pharmacy Week. In addition, you can reprint them for your pharmacy's patient newsletter or reproduce them to hand out with prescription orders in the pharmacy or at a health-related special event.*

## Understanding Your Medicines

Did you know that taking your medications properly is the best way to avoid future health care costs? Each year, thousands of people end up in the hospital, fail to get better, and spend more money than they have to simply because they don't take their medication properly.

Pharmacists can educate you about your medications, both prescription and nonprescription. The American Pharmaceutical Association, the national professional society of pharmacists, says that every person should be able to answer the following questions before taking any new medication.

1. What is the name of the medication, and what is it supposed to do?
2. When and how do I take it?
3. How long should I take it?
4. Does this medication contain anything that can cause an allergic reaction?
5. Should I avoid alcohol, any other medicines, foods, and/or activities?
6. Should I expect any side effects?
7. What if I forget to take my medication?
8. Is it safe to become pregnant or to breast-feed while taking this medication?
9. Is there a generic version of the medication that my physician has prescribed?
10. How should I store my medications?

Talk to your pharmacist for the answers. The more you know, the better you'll feel.

## How to Store Medications

The bathroom "medicine cabinet"—the place that most people keep their medicines—is actually one of the worst medication storage areas says the American Pharmaceutical Association, which represents the nation's pharmacists. Humidity in the bathroom can decompose medications and alter their effect. Pharmacists advise that medications be stored at room temperature, unless otherwise directed, and away from heat, moisture, and direct light. You should keep your medicines tightly closed in the original container and out of the reach of children. Because accidents can happen, keep the telephone number of your local poison control center handy.

Pharmacists also warn consumers to be mindful of expiration dates. Do not save outdated or undated over-the-counter medications or leftover prescription medicines, because they can change as they get older and cause harm. For example, giving your child cough medication containing codeine left over from a previous illness may do more harm than good. If water in the medication has evaporated, the codeine may be more concentrated and could cause disorientation. It's always best to ask your pharmacist if you are unsure about a medication's safety and effectiveness.

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## Pharmacists Urge Consumers to Speak Up During National Pharmacy Week

Where do you go when you have questions about medicines? Talk to your community pharmacist, the best and most accessible medication expert.

Pharmacists across the country are observing National Pharmacy Week, October 24-30, by urging the public to talk to their pharmacist about their medications. On Tuesday, October 26, consumers can call a nationwide, one-day toll-free information line at (800) OTC-2110 between the hours of 9:00 am and 6:00 pm Eastern daylight time and speak personally to a pharmacist about over-the-counter (OTC) medications.

Consumers will learn that the best place to store their medications is not in the bathroom medicine cabinet. Callers can get advice on choosing the best cough/cold remedy based on all the other medications they might be taking. Or they'll learn that, by understanding and following instructions, they can get better results from even common OTC medications like aspirin.

"Many times patients don't take the selection and use of over-the-counter medications seriously," said Lowell J. Anderson, APHA President. "Over-the-counter products are still very powerful, can cause side effects, and

can adversely interact with prescription medications. Consumers should seek the advice of a pharmacist to ensure they understand what they're taking."

Following the pharmacist's advice can both save money for consumers, and help lower the nation's health care bill by ensuring the safe and effective use of medications. Not following a medicine's instructions or discontinuing its use without your doctor's advice can lead to a more expensive treatment, such as surgery or hospitalization.

"When the patient keeps the pharmacist up-to-date on all prescription and over-the-counter medications being taken and asks important questions," added Anderson, "the pharmacist can monitor the patient's treatment and help guarantee a healthy result. The 'DIAL-OGUE' telephone service will provide valuable information, and will remind consumers that the pharmacist is always available to talk with them about their medicines."

The telephone hot line or "DIAL-OGUE" is being promoted jointly by the American Pharmaceutical Association (APHA) and the Aspirin Foundation of America.

## Sample Articles (continued...)

### Pharmacy Puts On A New Face



Pharmacy has evolved from a profession that only dispensed medicines to one that supplies comprehensive patient care services. That is why pharmacy has a new registered trademark that is to be the national symbol for pharmacists and pharmacies.

The "One Symbol for Pharmacy" represents pharmacists' focus on patient care and is popping up on store signs, prescription bags, medication literature, and right on top of the prescription container. Pharmacy has been identified by the traditional Rx symbol, which has been around since the Middle Ages. But, says Irving Rubin, the pharmacist who spearheaded the campaign for the new symbol, "obviously pharmacy practice and medications have changed. Today's powerful medicines require a pharmacist's intervention on behalf of the patient to make sure they are medicating properly. When patients see this new symbol in a pharmacy, they'll know that the pharmacists are delivering quality pharmacy services, such as monitoring for medication interactions and instructing patients on the proper use of their medicines."

The United States is not the first to see the value of a representative symbol. More than 30 countries have had their own individual symbols for years. The American Pharmaceutical Association has worked with Rubin, other national pharmacy associations, and pharmacists across the country to adopt and trademark a symbol.

### How to get the Most from Your Pharmacist

Who should you turn to with your questions about your medicines?

The answer should be your pharmacist. If not, you may not know what your pharmacist can do for you.

Once your doctor diagnoses your condition and chooses the appropriate medication for your treatment, your pharmacist takes over to make sure that you receive the maximum benefit from your prescription and nonprescription medicines.

Why is this so important? Taking your medication properly is the best way to decrease your health care costs. Thousands of people every year end up in the hospital, fail to get better, and spend more money than they have to because they didn't take their medication properly.

Pharmacists are medication experts—they do much more than count pills and pour liquids. For each prescription filled, your pharmacist must check to see that the information provided by the prescriber is complete, that the new medication will not interact with other medications that you are taking, that the medication and dosage are appropriate for your health con-

dition, and that you understand the proper way to take the medication.

Ultimately, you have the responsibility for managing your health care, but your pharmacist can help if you keep him or her up-to-date

about your health and medications you are taking. For this reason, it is important to use the same pharmacy for all of your prescription services, especially when seeing multiple doctors.

This ensures that your pharmacist has access to your complete medica-

tion history when checking for problems or possible interactions. You also should check with your pharmacist before taking any nonprescription medication. Even though they do not require a doctor's prescription, nonprescription medicines are powerful and can adversely interact with your prescription medications or badly affect another health condition. Make sure your pharmacist is aware of your allergies to any medications so adverse reactions can be prevented.

By working together with your pharmacist, you can be sure that your medications are taken safely, effectively, and appropriately to maintain your good health.



## Let's Talk



## Health Care Reform

*Continued from page 10*

There may be separate plans for HMO's and indemnity plans.

Any health benefits offered in addition to the standard benefit plan, must be offered and priced separately by carriers. The effect of the standard benefit plan is that all carriers in the small group market will offer the same benefits, deductibles and co-pays, and thus facilitate cost comparisons and the need for the carriers to compete on overhead administrative costs.

### Medical Care Data Base

HB 1359 authorizes HCACC to develop a medical care database. This database -- consisting of information on health services rendered by all health care practitioners -- will be used by HCACC to develop cost containment strategies. The data will also allow consumers, employers and insurers to comparison shop for health services rendered by all health care practitioners.

HCACC must adopt regulations to ensure the confidentiality of physician-patient privilege. HCACC will analyze this data and annually publish the total reimbursement for all health care services, the annual rate of change, variations in fees and utilizations on a statewide basis and by health service areas. The data base, once fully developed, should greatly assist in the control of health care costs. Another source of data will be developed to provide comparative evaluation of HMO's to insurance indemnity plans based on costs as well as quality.

Pharmacy will be one of the provider groups that must supply data to the HCACC. MPhA plans to request that data submission be through existing pharmacy software vendors to minimize or eliminate any additional costs for the provision of this data. Due to the large number of providers who must supply

data (an estimated 60,000), it is likely that pharmacy will be one of the later providers added to the database system.

### Payment System Oversight

The Health Care Access and Cost Commission is authorized to develop a payment system for health care practitioners. This payment system provides a framework for determining the ultimate price for health care services. Except under extraordinary circumstances described below, the marketplace and not HCACC will determine the final price of a health care service.

The payment system will be based on the following factors: the practitioners' resources (e.g., overhead and expertise); the value of the service (e.g., complexity); and a conversion modifier. The ultimate price for a service call will be arrived at by multiplying the numeric value of these three factors. The conversion modifier is the key to setting the dollar value of a service.

The HCACC will determine the numeric value for practitioner's resources and value of the service by current procedural terminology (CPT) codes. These codes are currently used by providers to bill for services and are similar to the standardized NDC codes pharmacists use for drugs. The market (practitioner's and payors) will determine the numeric value of the conversion modifier.

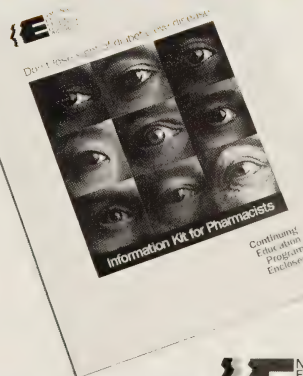
HCACC may establish health care cost annual adjustment goals for the cost of health care services and the cost for a particular CPT code. For example, the HCACC may set a cap on the price for a general physical. If spending exceeds these goals or caps, the HCACC through voluntary and cooperative arrangements with practitioners may make an effort to bring spending into compliance with this goal. If these efforts prove unsuccessful, HCACC may adjust the conversion modifier to force a reduction. Thus, HCACC will set the price for health care services only under extraordinary conditions. It is unclear at this point whether the

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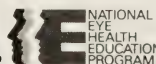
Of the 14 million people in America with diabetes, almost half will develop diabetic eye disease... a leading cause of blindness.

As a pharmacist, you can tell your patients with diabetes about reducing their risk of blindness through early detection and timely treatment of diabetic eye disease. You'll be helping them save their eyesight as well as winning their loyalty.

Order this free kit which includes a continuing education program, posters, counter display, brochures and more: call toll free at 1-800-869-2020 or write to National Eye Health Education Program, Box 20/20, Bethesda, MD 20892.



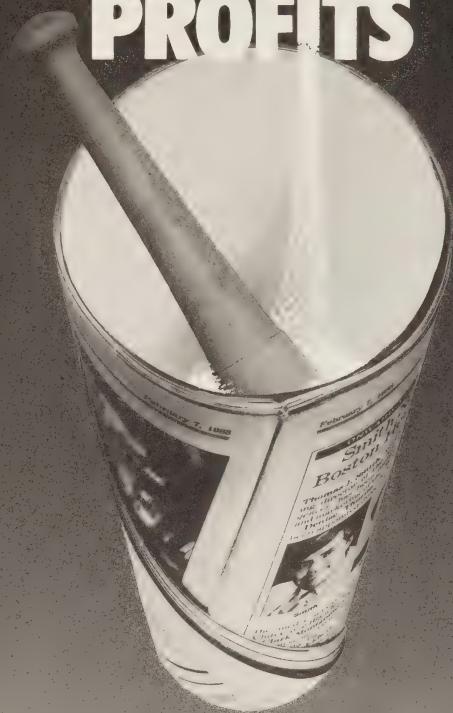
**Don't lose sight of diabetic eye disease.**



National Eye Institute, National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services

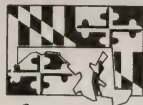


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HCACC will also increase compensation for a service if the existing price for that service is below the combination of the three factors.

### General Insurance Reforms

HB 1359 establishes a procedure to expand the small employer group insurance reforms to cover all employers and all policies. In addition, once the reforms cover the general market, an individual would be eligible to purchase health insurance after having been a resident of the state for 60 days.

HB 1359 sets two conditions that would trigger in these small group reforms to the general market if 60 percent of the population under 65 years of age would receive health care coverage through a fully insured plan with an insurer of health maintenance organization. Annually by October 1 the Insurance Commissioner must determine how many individuals under the age of 65 are in the fully insured market or are covered by an employer who would determine when the trigger has been met. The insurance reforms would take effect the second January 1st after the determination. Second, if the federal Employee Retirement Income Security Act (ERISA) is amended to allow states to control employee health benefit plans, then the reforms contained in HB 1359 would apply to the general market.

As a fail-safe procedure, HB 1359 permits the Insurance Commissioner to determine that "it is in the public interest" to raise the percentage under the first condition because expansion to the general market would be adverse to small employers or overall state health policy.

### Cost Containment Measures

HB 1359 implements various cost containment strategies. These include reducing insurance costs and encouraging administrative efficiencies and greater efficiencies in the delivery of quality care.

Insurers and HMOS's will be required to submit an annual report to the Insurance Commissioner. The report will provide information on their loss and expense ratios for Maryland, benchmarks of an insurer's efficiency. The Insurance Commissioner may require a carrier to file new rates if: (1) its loss ratio is below 75 percent; or (2) its expense ratio exceeds 20 percent for commercial insurers or health maintenance organizations or 18 percent for non-profit health service plans. This regulatory scheme controls administrative and regulatory costs for group health in a manner similar to existing regulation of property and casualty insurance.

In any action for damages in a medical malpractice case the health care provider is not liable for the payment of damages unless it is established that the care given by the provider is not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities.

In order to decrease administrative costs, the HCACC must designate practitioners and payors who will submit and receive claims and explanation of benefits electronically by July 1, 1995. The Commission will establish standards for the operation of one or more medical care electronic claims clearinghouses and may license such entities. It is these clearinghouses that pharmacists will eventually supply data to.

Health care practitioners are encouraged to voluntarily control cost by utilizing clinical resource management systems. Such systems permit practitioners to analyze their charges and utilization of services in comparison to their peers.

A 15 member Advisory Committee on Practice Parameters within the HCACC will be established to study the development of practice parameters for medical specialties and make recommendations on the adoption and use of such parameters.

The HCACC could adopt a practice parameter if the proposal includes supporting documentation that at least 60 percent of the specialists in the State affected by the parameter support the parameter, that the parameter will continue to provide a high quality of health care. The practice parameter would remain in effect for 3 years. Any practice parameter adopted by the HCACC could not be used as evidence of the standard of care in malpractice case.

### Summary

While there are many positive parts of Maryland's health reform statute that will benefit pharmacy employers, there are still questions as to how HB 1359 will impact the pharmacy profession. At this point, pharmacists and pharmacy permit holders will not have to pay additional fees to help support the Health Care Access and Cost Commission; MPhA will continue to lobby for the retention of this specific exclusion. It is likely that data from pharmacy claims will form part of the Maryland health care database; when, and to what extent given the massive quantities of claims that pharmacists process, has not been determined. Practice standards and guidelines will be required by the HCACC for health professionals. Pharmacy will no doubt be included. MPhA will be strongly in favor of using those principles and guidelines previously developed by the Association and published in the January 1993 issue of *The Maryland Pharmacist*. MPhA firmly believes that the profession, and only the profession, should determine and enforce standards of practice.

As these and other issues and questions are addressed by legislators and regulators, MPhA will be there to represent the interests of its members and pharmacy. **R**

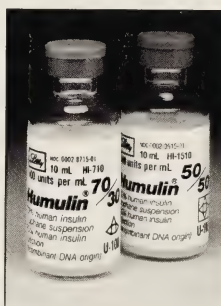
*This article is based upon materials from MPhA legislative consultant Robin Shaivitz, copies of House Bill 1359, and analysis prepared by the Maryland Retail Merchants Association and other business and professional groups.*




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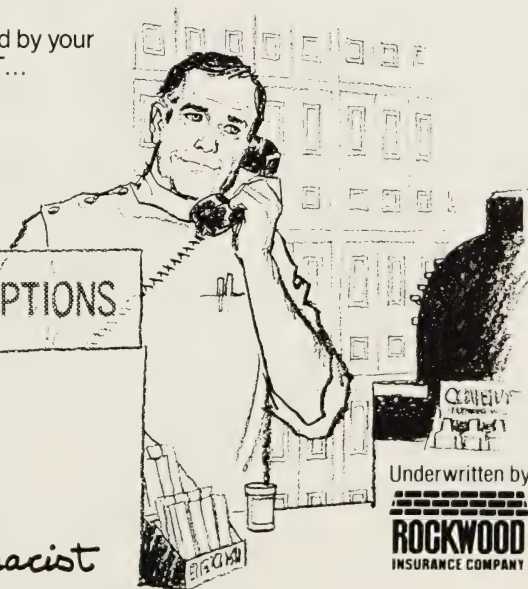
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# Everyone Sells Cough Syrup--Nobody is Liable

David B. Brushwood, J.D.



The case reviewed this month describes allegations by an apparent substance abuser that 12 pharmacies and 22 pharmacists should be held liable for having repeatedly sold the plaintiff Schedule V nonprescription codeine-based cough syrups, perpetuating his pre-existing substance abuse problem. The plaintiff alleged that the defendant's repeated cough syrup sales to him constituted negligence and a breach of the professional standard the defendants owed to the plaintiff.

The defendants filed a motion to dismiss the claim, stating that they owed no duty to identify an addicted customer and then refused to sell him a controlled substance. The trial court granted the defense motion.

On appeal, the court disagreed with the plaintiff's assertion that the pharmacists owed him the duty to refrain from dispensing to him the Schedule V nonprescription controlled substances. Relying on precedent from previous cases involving the dispensing of prescription drugs, the court held that the pharmacists owed no duty to the plaintiff to discover his addicted status; and failing knowledge of the plaintiff's addiction, they had no duty to refuse to sell to him.

This case leaves open the possibility that had the facts shown the pharmacists clearly knew the plaintiff was addicted, then perhaps the result would have been different.

This case also raises the interesting issue of the degree to which the OBRA '90 mandate will elevate pharmacy practice standards for the sale of OTC drugs. While OBRA '90 requires pharmacists to screen for clinical abuse/misuse of prescription drugs, there is no similar requirement expressly applicable to nonprescription drugs. Nevertheless, courts might apply to OTC dispensing the same rules that are applicable to the dispensing of prescription drugs. **R**

Based on *Kintagh v. Abbott Pharmacy et al.*, 1993 Mich. LEXIS 1385 (Mich. App. June 7, 1993).

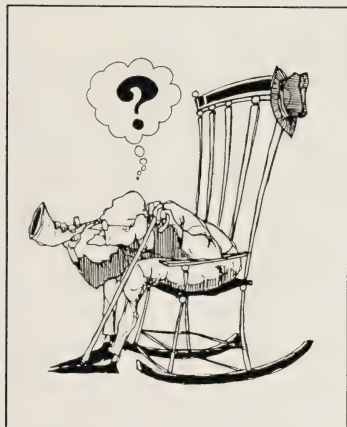
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## Changes in Medicare Part B

### A Special Alert from NARD

Robin Richardson, P.D., Vice President, HHC & Institutional Services, NARD

Tim Redmon, Director, Regulatory Affairs, HHC & Institutional Services, NARD



Do you ever sell blood glucose monitors? Nebulizers? Incontinence products? Wound care products? Anything else covered under Medicare Part B?

If so, the complete overhaul of the Medicare Part B system upcoming this fall will affect your practice -- and depending on the extent of your involvement in Medicare Part B, the changes could affect your pharmacy dramatically.

#### The New Regional Carrier System

Currently, there are 34 local Medicare carriers handling claims for services and products covered under Medicare Part B. Only about five percent of these claims are for home health care products, and as a result, many local carriers have exercised very little oversight in this area. What's more, coverage rules have been wildly inconsistent from one carrier to the next; the local carriers sometimes make incorrect coverage determinations and incorrect payments.

To correct these and other problems with the Medicare Part B system, the Health Care Financing Administration has devised a separate four carrier regional system to exclusively handle all durable medical equipment, prosthetics, orthotics, and supplies (together now known as CMEPOS) claims under Medicare Part B.

The four new DME regional carriers, or DMERCs, will begin operations on October 1, based on the a state-by-state transfer schedule.

The schedule for pharmacies in the Mid-Atlantic area are: District of Columbia, October 1, 1993; West Virginia, November 1, 1993; Maryland, December 1, 1993; Pennsylvania and Virginia, January 1, 1994.

#### So What's New?

Under the new regional carrier plan, the way you do business with Medicare will change in nearly every respect. For example:

- A new carrier will be handling your Part B claims.
- You must have a new Medicare supplier number. Your current supplier number(s) will no longer be accepted; you will not be reimbursed using your current supplier number.
- New medical review guidelines will change the way Part B supplies are covered; based on proposed guidelines developed by the DMDERS, in most cases, coverage will probably be more restrictive than under the current local carriers.
- All claims must be sent to the carrier for the beneficiary's state of residence -- regardless of what state you are sending the claim from or where your pharmacy is located.
- New certificates of medical necessity forms will be in use. the CMNs will be standard from one region to the next and will be available in electronic formats.



## Who are the DMERCs?

So who do you send your claims to after the implementation date? Here is a list of the new or reassigned processors for Medicare Part B claims.

*Region A:* The Travelers Insurance Company, Hartford, CT

*Region B:* AdmiraStar Federal, Inc., Indianapolis, IN

*Region C:* Palmetto Govt Benefits Administration, Columbia, SC

*Region D:* CIGNA, Nashville, TN  
Maryland, Virginia, West Virginia, and the District Columbia are all in Region B. Pennsylvania is in Region A.

## Filing Non-assigned Claims

The requirement that pharmacists and other Part B suppliers submit claims for Medicare beneficiaries -- even if those claims are non-assigned -- has been a source of annoyance for many retail pharmacists since it went into effect in September 1990.

If your pharmacy's sales of Medicare Part B-covered items are very low and you have no interest in retaining this business -- If you essentially don't want to be a Medicare supplier -- now is your chance to "opt out" of the program.

NARD has worked with the Health Care Financing Administration extensively in recent months to work out an exemption for very low volume Medicare Part B suppliers.

According to HCFA, to be exempt from the legal obligation to submit unassigned claims for Medicare beneficiaries, pharmacists can choose not to fill out the new supplier application form. If you don't fill out the form, by definition you are not a supplier and you then are no longer required to file unassigned claims. If your pharmacy decides to take this approach, remember that beneficiaries cannot be reimbursed by Medicare for the items that they buy from your pharmacy. You may lose these customers.

If, instead, you want to continue to be a Medicare supplier, you are still

obligated to file unassigned claims on behalf of Medicare beneficiaries.

## Changing Coverage for Supplies

The upcoming carrier transition will also mean a completely new set of rules governing how and under what circumstances covered item will be reimbursable, called "medical necessity guidelines." The DMERCs issued draft medical review guidelines for all covered items in April and May.

In theory, these carriers have no authority to change Medicare coverage. But in reality, the draft guidelines would alter Medicare coverage dramatically. Some "covered" items -- electric beds and electric lift mechanisms for example -- will *never* actually be eligible for reimbursement, because the DMERCs have determined that they are never medically necessary. Draft guidelines for the four regions are essentially identical.

Here are just a few examples of proposed changes in "medical review criteria" that could affect your business.

### ● Use of Items "In the House."

Durable medical equipment would be covered only when it is medically necessary for use in a patient's home. Equipment or features needed for use outside the home, or those serving a "convenience function" -- including folding walkers and portable oxygen -- would not be covered.

### ● Home Blood Glucose Monitor Supplies.

More than one bottle or box each of strips and lancets per month would rarely be "medically necessary." Insulin-dependent diabetes patients would have to limit their testing to 50 tests per month -- an average of 1.7 tests per day -- although many patients require more intensive self-management. Urine test reagent strips or tablets would not be covered; separate payment for normal, low, and high calibrator solution/chips would not be allowed. NARD believes that these proposed policies

would make it more difficult for diabetes patients to control their glucose levels, leading to unnecessary hospitalizations.

● **Nutritional Therapy.** Nutritional therapy would be covered only for patients with a permanently non-functional GI organ. Supplemental nutrition, or the use of enteral nutrition for patients with cognitive disorders such as Alzheimer's disease, severe dementia, and even neurologic conditions would be considered "not medically necessary."

● **Incontinence Supplies.** Coverage for indwelling catheters (foley type two-way) would be reduced from two to one per month. Insertion trays for sterile intermittent catheters and more than weekly replacement of irrigation trays would be considered "not medically necessary."

● **Ostomy Supplies.** Only ten drainable pouches per month would be covered. (Current policy is based on physician order and medical necessity at 30-plus pouches per month if medically necessary.)

● **Wound Care Products.** Secondary dressing and other medically necessary products would not be covered, such as medicated gauze, composite dressings, and wound pouches.

## What Steps Is NARD Taking?

Throughout the regionalization planning and implementation process, NARD has been working aggressively with the Health Care Financing Administration and the medical directors of the DMERCs on the regionalization process.

Our commitment to representing pharmacy on this issues involved literally dozens of meetings, hours of informal discussions with key officials, more than 90 pages of detailed comments on the DMERCs proposed medical review guidelines, along with special educational sessions and in-depth coverage for NARD members.

*Concluded on Page 31....*

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call John Ayd at (410) 661-2383 for details.

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MPhA members can place a classified ad in *The Maryland Pharmacist* and reach more than 1,400 pharmacists for free.

Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50.

To place an ad, send your type-written copy to MPhA, 650 West Lombard Street, Baltimore, MD 21201-1572. Or you can FAX your ad to (410) 727-2253.

## Changes in Medicare Continued from Page 30

In addition, the association has asked HCFA and the regional carriers to resolve all significant issues before the new carrier system takes effect.

### What You Should Do

Pharmacies should take immediate steps to protect their cash flow in the months to come. If not, reimbursements could come to a complete halt once the regional carrier takes effect in your state this fall.

If your pharmacy has a Medicare supplier number with your local carrier, you should have received a supplier application kit from the Medicare National Supplier Clearinghouse. You must fill this out immediately. The longer you delay, the longer it will take to receive a new supplier number, and the longer it will take to be reimbursed under the new system. (You must have a separate application for every one of your locations.)

If you haven't received a new supplier application kit, call the National Supplier Clearinghouse immediately

at 800-851-3682.

Carefully track your current claims and your Explanation of Medicare Benefits (EMOBs) you receive back from your local carrier. Local carriers might not be as concerned as they once were about processing your claims in a timely and accurate manner.

Get a copy of the DMERCs' draft medial review guidelines. These guidelines are available through NARD.

Attend educational meetings held by your regional carrier. Call your regional carrier for information on meetings in your local area.

Inform your patients about upcoming changes and how these changes will effect them.

### What Else You Can Do

Stay informed...

Have a voice in changes affecting your practice...

Gain the representation you need by joining NARD's specialty divisions.

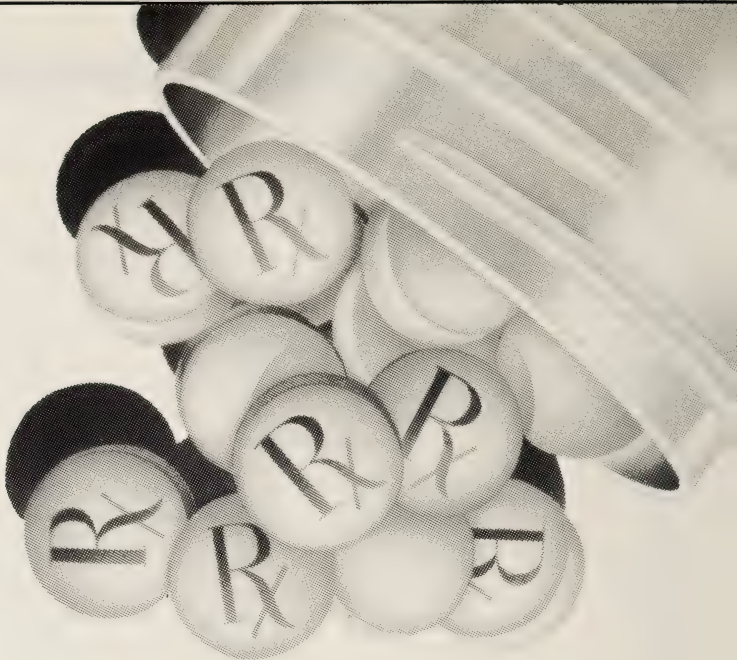
Since January 1992, NARD has provided expanded representation for pharmacists in the home health care and long-term markets through two new divisions of NARD membership: The Division of Home Health Care Pharmacy Services and the Division of Long-Term Pharmacy Services.

In depth information on the regional carrier process and other issues important to independent home health care, long-term care pharmacies, and community pharmacies are covered in depth in the divisions' two specialty monthly newsletters *HHC Pharmacist* and *LTC Pharmacist*.

For more information, call NARD at (800) 544-7447 or (703) 683-8200.

**R**





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# The Maryland Pharmacist

VOL. 69

OCTOBER, 1993

NO. 10



*Breaking Barriers  
Pharmacists and the ADA*



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# The Maryland Pharmacist

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Number 10

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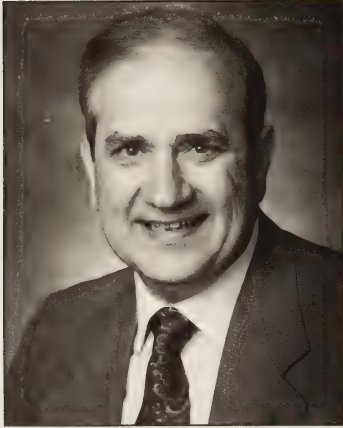
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## President's Commentary

*Howard Schiff, P.D.*



The Clinton Health Reform Plan presents a mixed bag for pharmacy. The proposal has been presented but no legislation has been introduced. When that happens, the final results will not be known for some time. There are too many variables to do more than speculate what the outcome will be. Although discriminatory pricing by pharmaceutical manufacturers is eliminated and the exemption from antitrust laws enjoyed by insurers is repealed in the proposal, the HMO's -- chiefly owned by the insurance industry -- appear to be the center piece of the whole plan.

What is certain is that for the first time in the history of this country, health care will be a right of citizenship and not a privilege of wealth or position. To be fair, some of us have been provided with cradle to grave health benefits because of our social status; this is the first time that universal access to health care has been proposed and apparently accepted by the American public. This is as significant a change as was the acceptance of Social Security in the 1930's.

How will pharmacy be affected? We don't know for sure. What seems to be certain is that there will be many more prescriptions for many more people. The Clintons seem to respect pharmacy and pharmacists and want us to be more involved in the health care process. This is a step on the way to pharmaceutical care. However, between regional health alliances and health plans that will control access to care and providers, we will all be indirectly employed by the government. Whether independent pharmacies, small chains, large chains or community pharmacy in general will survive is unknown. Whether major hospitals will swallow or eliminate smaller hospitals is also unknown. Every pharmacist, in every practice setting, must pay attention to this health reform proposal as it proceeds through Congress.

Think of this scenario 30 or 40 years in the future. Some bright young politician has a brainstorm and envisions that it would be advantageous to have storefront pharmacies in the community instead of a concentrated in one gigantic regional medical center. Some old guy or gal who graduated before the turn of the century will have to remind him of what we had. **R**

# The ADA's Impact on Pharmaceutical Care

*Michaeline R. Fedder, M.A., Deputy Executive Director  
American Heart Association - Maryland Affiliate*



On July 26, 1990 President Bush signed into law a sweeping piece of legislation, the Americans with Disabilities Act (ADA). The ADA contains five major parts or titles, one of which, Title III, has implications for pharmacists.

The essence of Title III is that people with disabilities must have access to the same goods, services and facilities as other people; they may not be excluded, denied services, segregated or otherwise treated differently. Under the law, people are considered disabled if they have a physical or mental impairment, have a history of an impairment or are considered impaired in a way that limits any of life's major functions such as walking, talking, seeing, hearing, working or learning.

As Americans first became aware of ADA, we reacted to the requirements dealing with structural accessibility: ramps leading to entrances, bathrooms with wide doors, lowered sinks and guide rails and aisles and shelves that can be utilized by people in wheelchairs. These requirements were onerous enough, often necessitating alterations to existing facilities.

A major concern, however, has nothing to do with physical accessibility. This concern is communication: making drug and other product information accessible to and usable by people with "communication disabilities."

## Relevance to the Pharmacist

Pharmaceutical care, reinforced by the requirements of OBRA '90 places responsibility on the pharmacist to

counsel patients so that drug therapy is maximized.

The usual and customary procedure is to place a sticker on the prescription container, perhaps provide a patient information leaflet and ask the patient if there are any questions.

But suppose the patient is visually impaired. Suppose the patient can't read. Suppose the patient is hearing impaired. Suppose the patient is aphasic. Then these usual and customary procedures may not work.

## Getting Started

As health care providers who want to maximize their effectiveness and render the best possible care to all of their patients, we have to begin to broaden our communication strategies to deal effectively with patients, with physical impairments and/or learning limitations. The following plan is suggested to help the pharmacist offer services to "communication-impaired" patients.

**one** Establish the goal, in writing, of "making information accessible to an usable by people with communication disabilities."

**two** Designate, in writing, a responsible person to coordinate planning and implementation of ADA compliance efforts.

**three** Involve all staff in planning and implementing ADA

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compliance efforts.

**four** Identify, in writing, current obstacles that limit accessibility to services.

**five** Describe, in writing, steps to be taken to achieve compliance; include a time line.

#### Strategies for Achieving Effective Patient Communication

*For individuals who are visually impaired:*

- Make sure that counseling areas in the pharmacy are well lighted.
- Provide large-type instruction sheets - these may be prepared using standard enlargement capabilities of copying machines.
- Be sensitive to ink and paper colors as you develop or select patient education materials. Black ink on bright, white paper is easiest to see. Do not use colored ink.
- Be prepared to provide patient education materials in braille. This is not as hard as you may think, since local resources (i.e., services for the blind) are usually available.
- Prepare patient education materials on audio tapes. These may be given or loaned to the patient.

*For individuals who are hearing impaired:*

- Make sure that the counseling area is quiet and free of extraneous noises.
- Have the counseling area fitted with an assistive listening device.
- Use communication boards with words and symbols, blackboards with chalk or newsprint with magic markers.
- Select captioned videotapes

*For individuals who are reading impaired:*

- People who cannot read are impaired. Don't assume all your patients can read. Illiteracy is an easy condition for patients to hide and for health care professionals to overlook. In reality, poor reading skills are found in every part of the country, in every walk of life and among every population group.
- Be aware of the reading level of patient education materials you have been using. A good test is the SMOG Readability Prediction Formula. The box on page eight shows how to use this formula.
- For low literacy individuals, select materials which are at fourth grade level or below. These may be available from voluntary health agencies.
- For non-readers or language impaired patients, provide visual information. Prepare pictures or diagrams that are visually clean and simple.
- Keep messages short, simple and specific.

Individuals who cannot speak:

- Install a TDD (text telephone).
- Use paper and pencil for face-to-face communication.

#### Taking the Next Steps

Once you are sensitized to the need for patient accessibility, you may begin to use your own creativity and ingenuity. Changes must not produce an "undue hardship" on business... but many changes can be made at little or no cost.

Can a patient enter your pharmacy in a wheelchair? If a ramp is too costly, consider installing a doorbell at wheelchair height and providing service at your front door. Phones, fax machines, and delivery also may be used. **R**

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1. Communications and the ADA. American Speech-Language-Hearing Association, Rockville, MD
2. ABC's of Voluntary Compliance with the ADA - Implementing ADA - Implementing ADA - Where to start. U.S. Department of Health and Human Services. Dallas, Texas.
3. Is Reading Ability Affecting Your Patient's Therapy? *The Maryland Pharmacist Association*. Baltimore, Maryland.
4. SMOG Readability Prediction Formula. Baltimore County Public Schools. Towson, Maryland.

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# SMOG Conversion

To determine the readability of material (SMOG content), the following table can be used:

- Select 30 sentences from the item you are analyzing.
- Count words of three or more syllables
- Use information presented in the table below to find the grade level or take the square root of the word count (three syllables or more) and add three.

Total 3 Syllable Word Count	Grade Level	Total 3 Syllable Word Count	Grade Level
0-2	4	57-72	11
3-6	5	73-90	12
7-12	6	91-110	13
13-20	7	111-132	14
21-30	8	133-156	15
31-42	9	157-182	16
43-56	10	211-240	17

## Getting Help

Following even a few of the suggestions noted in this article may seem overwhelming at first. But help is available from:

### President's Committee on Employment of People with Disabilities

1331 F St., NW, Suite 300  
Washington, DC 20004  
Phone (202) 376-6200;  
TDD: (202) 376-6205.

*This advisory committee can provide information on the Americans with Disabilities Act and on employment of individuals with disabilities.*

### Job Accommodation Network

809 Allen Hall  
West Virginia University  
Morgantown, WV 26506  
Phone: (800) 526-7234

*Free service provides information on the ADA including dollar cost of various accommodations that can be made to assist people with disabilities.*

### American Speech-Language-Hearing Association

10801 Rockville Pike  
Rockville, MD 20852  
Phone (800) 638-8255 (V/TDD);  
(301) 897-5700 (V);  
(301) 897-0157 (TDD)

**State or local Vocational  
Rehabilitation Agency, League for  
the Handicapped, Federation of the  
Blind, School for the Blind, Office  
of Disabilities, etc.**

### Regional Business and Technical Access Centers

*Hint: Once you make the first call, ask the person you've reached to suggest others in the community who might be helpful!*

# Dickinson's Pharmacy

*Can States Effectively Regulate Mail-Order?*

*Jim Dickinson, Editor, Dickinson's Pharmacy Newsletter*

Technicians are illegally calling prescribers and interpreting prescription so successfully at one of Medco's Florida facilities that the company plans to expand their role, according to a pharmacist who worked for three years at the facility. The plant's ratio of pharmacists to technicians has been raised to an effective 1:6, far in excess of the state's 1:2 maximum, Pharmacist X says (we are shielding the pharmacist's identity at the pharmacist's request).

Beyond that, current testing of robotics by Medco could lead to fully mechanized dispensing through the installation of such machines as the Komech 200, which reportedly can output up to 8,000 prescriptions an hour.

Pharmacists will still be valuable-- but in reduced numbers-- for calling prescribers in Medco's apparently lucrative "Prescriber's Choice" program that persuades doctors to change drug choices in favor of products on which Medco has secured an exclusive price break or kickback. Breaks like \$2.58 for Aerobid inhaler System 7 gm that costs independents around \$33, according to price-discrimination lawsuits filed in August against Medco, Bergen Brunswig, McKesson and four manufacturers by Fred Mayer's Pharmacy Planning Services Inc.

Then there are outright kickbacks, such as the \$250 that one company is known to be paying for each Rx that Medco pharmacists switch from a competing product to its brand in the Prescriber's Choice program in exchange for a guaranteed share of

market; according to Pharmacist X, such kickbacks effectively reduce Medco's acquisition cost nearly to zero and may explain in part the sharp rise in the drug's price to non-Medco accounts.

Since Merck and Co. decided to buy Medco for \$6 billion, the future has never looked bleaker for community pharmacy. As Mayer put it: "This is do or die."

*All of this points to  
a crisis of a practice setting  
and a business model  
in the future.*

To give it its due, America's most-respected company did extend a fragrant olive branch to pharmacy in the form of a merger-celebrating news statement that promised "programs with retail pharmacists that encourage and reward drug utilization management-- valuable information to patients, formulary compliance and other clinically beneficial initiatives." These and other laudable goals for Merck-Medco's relationships with other interested constituencies were labeled "Coordinated Pharmaceutical Care."

Unfortunately, none of the Merck-Medco publicity identified exactly who will be the "coordinator."

Since it has become obvious that Merck's real interest in the merger is to gain access to Medco's huge data bank on the drugs prescribed for its 33 million patients, and since Merck showed no interest in Pharmacist X's

evidence of Medco law-breaking when it was offered to the company's lawyers, and since Medco CEO Martin J. Wygod told the news media Medco would continue to operate as an autonomous unit even after its acquisition by Merck, we must assume that the coordinator will be Medco.

That, frankly, is a chilling thought. It's all the more chilling when one considers Pharmacist X's inside-dope on Medco as I have done for the past seven years or so.

Florida allows one pharmacist to one technician, with a second technician permissible by special waiver if that technician is limited to computer data-entry. However, a November 11, 1992 Medco interoffice memorandum by supervisor Chris Asaro advised that the company's ratio henceforth will be 1:3, which Pharmacist X says works out in practice to mean peaks as high as 1:6 when client tours or board inspections are not taking place.

When they are, job stations are rapidly switched during the five minutes' notice that the facility gets before each tour or inspection; technicians leave the pharmacy area and hide in other rooms.

Pharmacist X says regulatory inspections are regarded as a joke by Medco pharmacists because the facility is so organized that inspectors simply don't know what they're looking at. "You have to work there at least two weeks before you have the slightest idea what's going on," he told us. "When a board member comes into a community pharmacy, he knows exactly what to look for ... the



sheer volume of it. He doesn't know anything about screening assumptions."

Screening assumptions, Pharmacist X explained, are plain-paper management memos to technicians that instruct them on what assumptions to make when data is missing from prescriptions. For example, if the dose is missing, assume "take as directed."

The significance of the plain paper for such memos should be obvious; management can always deny their authenticity if challenged by a regulator. And how to document for prosecution purposes the fact that technicians make doctor calls that pharmacists should make, to interpret prescriptions? "It would take 160 agents to monitor all the calls that go out of that place -- and what would a \$100,000 fine matter to Medco, anyway? It would be just a cost of doing business."

Within two years, he predicts, few pharmacists will be engaged in "Prescriber's Choice" Rx-switching and fielding patient inquiries/complaints.

Why don't more Medco pharmacists defect and tell their stories? The money is too good, and Medco configures its internal operations in such a way that employees seldom get to see "the big picture." In addition, employees are kept fearful of consequences to themselves and their families if they violate Medco employment rules. Many believe, erroneously, that Medco has the ability to prevent their employment elsewhere if they are fired; management intimidation is apparently pervasive, since most

defectors insist on anonymity and many seem to fear for their lives.

All of which paints a picture of a practice setting that is beyond public scrutiny or control. Although Pharmacist X brought his evidence before the Florida Pharmacy Board in March, no publicly visible action had been taken by August. Board executive director John R. Taylor told me he was prohibited by state law from confirming or denying the existence of any investigation.

Pharmacist X and others familiar with the Florida board say nothing is being done because the job is too big for any state agency. And even if it did muster enough resources to do this one job, what about all the other mail-order facilities in all the other states? Would any number of fines stop these high-profit, competition- and greed-driven violations?

All of which paints a frightening picture of Medco and similar operations as darkened, closed cells feeding and growing in a pharmacy world that by stark contrast is extremely open, accessible, publicly accountable -- and perhaps a little too unsuspecting for its own good. Now this shining, most trusted world of pharmacy may be crumbling as the mail-order monster grows with the help of collaborators like Merck and invisible regulation.

To quote an old adage: "Justice must not only be done -- it must be seen to be done." In mail-order's case, this rule is clearly inoperative. The only facts we know about these companies are those they choose to let us know.

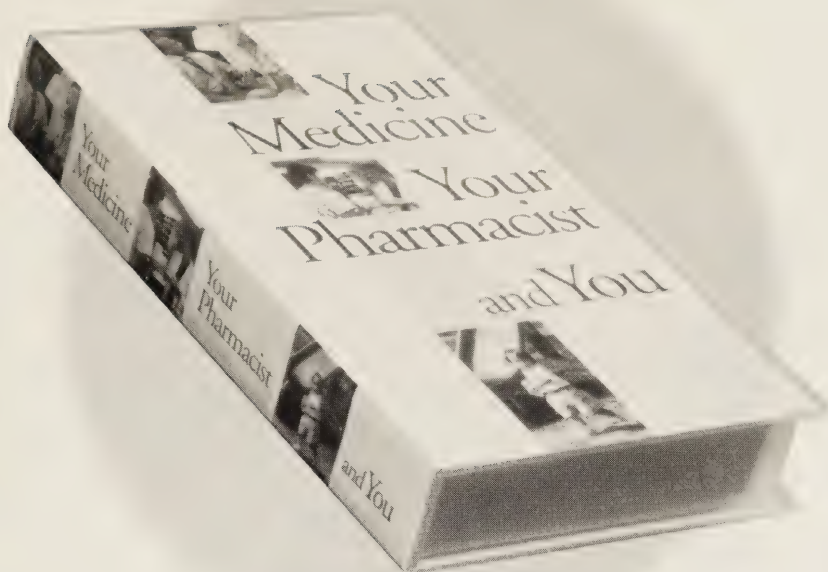
In a world of publicly-accountable

health care companies, this has serious public safety implications. If Florida's pharmacy board is unable to find 160 investigators to monitor Medco's phenomenal telephone operations for possible illegalities -- a regulatory task that finds no parallel need in community pharmacy -- who will protect the public?

Since nearly all of the drugs dispensed by these mail-order facilities are released into interstate commerce, the federal Food and Drug Administration would appear to not only have clear legal authority to intervene, but to also be the only practical source of effective regulation to openly and visibly protect the public from operators for whom illegal conduct has apparently been built into their routine procedures. For the third time in five years, I have again asked FDA to accept this responsibility.

If you have any information on this subject that you believe would benefit the profession, please send it to me at P.O. Box 367, Las Cruces, NM 88004. Include \$45 if you'd also like a year's subscription to my monthly newsletter. **R**

**Editor's Note:** The views expressed in "Dickinson's Pharmacy" are those of the author and do not necessarily represent the views or positions of the Maryland Pharmacists Association. The publication of this article should not be considered an endorsement of positions or recommendations presented.



# Here's A Coming Attraction That Should Attract You

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# Legal Drugs For Sale on the Streets

David M. Hammel, Investigator, Maryland State Police



This article is not intended to question or prevent the legitimate treatment and dispensing of controlled dangerous substances; I hope you will read it and gain some insight into the illegal (street) market for prescription drugs.

Do you know where the drugs you dispense really end up? Do you know how much money can be earned on the street from prescription drugs? Prescription drugs, generally controlled dangerous substances, are being used like traditional street drugs at an ever increasing rate. This increase can be explained in a number of ways.

Obtaining a prescription drug is easy and the quality of the drug is guaranteed by the Federal Food and Drug Administration (FDA). In every neighborhood there is a pharmacy, and that is the source for "legal/illegal street drugs". I refer to them as "legal/illegal street drugs" because the sale, possession, and use is legal on face value; however, the end result is very illegal.

## Professional Patients

Physicians and dentists are often placed in a very tough situation by a person seeking a prescription. The prescriber has a responsibility and duty to care for the patient. These doctors do not want the patient to experience more pain than is necessary. These doctors want the patient to be treated as he or she would want to be treated. The patient however wants a very different thing -- *drugs*.

The drug seeking patient can be very convincing, saying all the right things and making all the right complaints. These people are "professionals" at manipulating the health care

professional so that they can get a prescription. This knowledge and ability on behalf of the "patient" forces the doctor to make a tough decision, whether to prescribe drugs or not.

Once the prescription is issued, the person goes to a pharmacy to get the prescription filled. It doesn't matter what pharmacy they go to because, after all, it is a "good" prescription. If the pharmacist inquires with the prescriber, they will verify the legitimacy of the prescription. Once the filled prescription is obtained, the patient is loose on the street with a ready supply of drugs for sale.

## Small Investment - Big Profits

The sale of prescription drugs through illicit means can be very profitable especially if the "patient" has a prescription plan or receives Medical Assistance. Their investment is minimal and the outcome can be substantial. For example, a person steals a Medical Assistance prescription form and forges a prescription for one hundred hydromorphone (no out of pocket expense for a doctors office visit). The person then recruits an elderly and sick looking individual to walk the prescription into a pharmacy (this person will get a pill or two if successful, still no out of pocket expense). The pharmacist fills the prescription feeling sorry for the "sick" man or woman without verifying the prescription, charging Medical Assistance with the bill, except for the copayment. The person leaves the store and gives the prescription minus two pills to the forger. These pills are then sold for \$25 to \$35 per pill on the street. The forger takes in more than \$2,000 on this one pre-



scription.

These people will repeat the process of visiting doctors several times a day, stockpiling the legitimate prescriptions, stolen blanks and the substances obtained. Records seized from individuals during police investigations have shown that professional patients may see as many as twenty different prescribers in a single day. These people generally keep records so as not to forget who they went to and when. These records often reflect which doctors will write a script and which ones will not. This helps the offender to maximize the efficiency of their time. Even if the doctor will not write a prescription, sometimes the individual will obtain the doctors' registration and DEA number from within the office to be used later in getting a prescription.

Personal phone books have been recovered from offenders where various doctors' DEA numbers have been filed away under the alphabetical listing in lieu of the phone number.

### Protecting Yourself

I caution every provider, whether you actually write the prescription or your name and DEA number just get used, you do not want to be known on the street as an "easy mark" or "script doctor" because you will be overwhelmed with people trying to get you to issue prescriptions for no medical purpose.

Another method of obtaining prescription drugs is through a forged prescription. The "patient" goes to a unsuspecting doctor or dentist and obtains a benign prescription (something with no street value). The "patient" then copies the prescription,

whites out the drug name and issues their own prescription for a drug that can be sold on the street.

This is a very big problem. The "patients" are generally as knowledgeable about drugs as are the doctors and they can write a prescription as well as most physicians. I have seen forgeries that even the doctors themselves could not determine if they had written it or not except for the fact they did not dispense the particular drug according to the patient file in the office.

Generally the drugs of choice are in Schedule II of the Drug Scheduling Table, which requires a written prescription upon dispensing (Dilaudid, Percocet, Percodan, Oxycodone, etc). Schedule III drugs present another problem to the pharmacist. These substances can be dispensed on a verbal prescription by the doctor. The "pill pushers" have become all too familiar by the offender representing himself as a doctor placing a prescription.

The doctor will provide a call back number for verification but instead of it being the doctor's office it will be a pay phone, a house or sometimes a bad number. Many pharmacists are too busy to verify the prescription and it is ultimately filled, once again placing legal drugs on the street for illegal sale.

In Maryland, this problem is vast and deserves the attention of every physician, dentist, and pharmacist. You each have a moral duty to treat your patient, but you may want to ask yourself is this a patient, or a "patient;" and, is this prescription for the patient, or "for sale on the street."

Some helpful ways for doctors to guard against "the patient," and the

inappropriate issuance of a prescription:

- Be leery of first time patients that only complain of pain and the only treatment desired is a prescription.
- Maintain prescription pads in a secure area.
- Refrain from having the DEA number printed on the prescriptions. (The number is not needed on all prescriptions and you can write the number on necessary prescriptions.)
- Maintain records, or even photocopies, of prescriptions issued in the patient file.
- Check your records to be sure that you are not issuing a prescription before the proper time or in an excessive amount.
- If a patient seems in question consult with other doctors in the area to see whether or not the person has been to them with the same complaints.
- Refrain from issuing prescriptions to patients of associates in your office on the patient's request without consulting the patient file.

### Tips for Pharmacists

Some helpful ways for the pharmacist to guard against filling a "bad" prescription:

- If the prescription is in question always contact the issuing doctor.
- Be leery of persons with narcotic prescriptions coming into the pharmacy near closing time.
- Be suspicious of prescriptions from doctors not in the area of your pharmacy or the patient's residence. Most people get prescriptions filled near work, home or the

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doctor.

- If you do not feel comfortable filling the prescription, decline to fill it. It is your right not to fill any prescription and you are accountable for the ones you do fill.
- When a call-in prescription is received, look the doctor up in the phone book and use that telephone number to verify the prescription, not the one provided by the caller.
- If you receive a confirmed forgery do not give the prescription back to the person, maintain possession of the prescription and write down a description of the person presenting the prescription. Any information that you can record will be helpful in apprehending the offender.

This is not a totally inclusive list of ways people obtain prescription drugs; but these are the most used ways. The initiative and success of an offender is only limited by their imagi-

nation. These cases are often very difficult to bring to prosecution but if you are careful in the prescribing and dispensing of prescription drugs "the patient" will never have the opportunity.

If you have any information regarding prescription violations, suspect anyone of committing these offenses or need any additional information please contact the Maryland State Police, Bureau of Drug Enforcement, Drug Diversion Unit at (410) 290-0050. **R**

### **About the Author**

The author has been a member of the Maryland State Police since 1985 and has been assigned to the Bureau of Drug Enforcement since 1988. In 1989 the Drug Diversion Unit was established and he was one of the initial members. He has a B.S. in psychology from the University of Maryland and has attended many

special training courses on investigative techniques and drug diversion. He has instructed and given lectures on drug diversion on numerous occasions and is a member of the Board of Directors for the National Association of Drug Diversion Investigators. He is considered an expert in the field of drug diversion.



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*Scott Rickards*

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# Personal Strategies

## *Private Pension Plans for the 1990's and Beyond*

Peter A. Winer, Mayer Steinberg & Yospe



An uncle of mine wants to be sure that I save for retirement and approached me with the following "deal." He offered to loan me 28 cents for every dollar I invest for retirement. For example, if I planned on saving one dollar, He'd loan me 28 cents and I'd only have to put in 72 cents.

There were a few catches. First I'd have to agree not to touch the money until I'm 60 years old and I would pay him back 28 cents on every dollar in the account when I take money out, not just the dollars he loaned me.

Next I'd have to agree that he could demand any portion of my account that he wanted when it was time to pay him back. It might be 28 cents on the dollar. It might be 50 cents, and it's on the value of my entire account. The more my account grows, the more I have to pay him. If I break my agreement not to touch the account before I'm 60, I have to pay him another 10 cents on every dollar in my account, in addition to whatever else he demands. He's very serious about this being just for retirement.

I asked him if there was a "cap" on the loan rate. He said no, but that it probably wouldn't be too much higher than 50% or so. I politely declined his offer and wondered who would get involved with an account like that. But my uncle has convinced millions of Americans to take this deal. It's true.

Uncle Sam is a great marketer. He calls these loan plans IRA's, Keough's, SEP's, Pension and Profit Sharing plans and 401K plans. This "loan" is today's tax-deduction, paid

back tomorrow at whatever the future tax rate is, based on the full value of your account at compound interest.

Have you ever thought about what you give up in order to get this small tax loan today? Most people agree that taxes are increasing, so the likelihood is that you take a 28% - 36% deduction today, paid back at 40% - 50% or more tomorrow.

Let's use a simple IRA for an example. (Table 1) At age 50 you set aside \$2,000 per year for ten years. In a 28% tax bracket, you receive a loan (tax deduction) each year of \$560, for a total loan of \$5,600 over ten years. Over that same ten years your account would grow to \$28,973 if you earned 8% interest. At that point, you have an IRA worth \$28,973. If you close the account you owe taxes. At a 50% future tax rate that would be a \$14,486 tax bill, leaving you with \$14,486 after tax. Since your total after tax deposits were \$14,400 (\$2,000 minus \$560 equals \$1,440, times ten) that leaves you with a ten year gain of \$86. If this example were for someone younger than age 50, there would be an additional 10% penalty tax, which would turn this small gain into a loss. Even if the average tax rate only rises to 38% over the next decade, your \$28,973 will into \$17,963 for a gain of \$3,526 over ten years.

There is an alternative to this.

Tax rates are relatively low right now. Even under the new tax law, they're still lower than they have been for a long time. With that frame of reference it makes sense to accelerate income now. It's preferable to pay taxes at 28-36% today instead of 50%

Annual deposit	\$ 2,000
28% Tax Deduction	\$ 560
Net After Tax Deposit	\$ 1,440
Total 10 Yr. Net Deposits	\$ 14,400

Account Value Year 10  
(Assumed 8% return) \$ 28,973

Taxes due at 50% rate	\$ 14,486
Net Account Value	\$ 14,486
<b>Net Gain</b>	<b>\$ 86</b>

Taxes due at 38% rate	\$ 11,009
Net Account Value	\$ 17,393
<b>Net Gain</b>	<b>\$ 11,010</b>

**Table One**

tomorrow.

So now what? What do you do with that money that you might put into 401K or Profit Sharing plan? Establish a private plan.

With a Private Pension Plan you do not take a deduction on your deposits. As you've seen you're better off paying taxes now. This account is sheltered so you do not pay any taxes on the earnings while they remain in the account. There are also no government contribution limits. You decide how much to save is right for you.

Since there is no IRS red tape, you may also decide what purpose you want to save money for. You could use your plan to help fund your child's college education. Or to save money for your daughter's wedding. Or for your retirement. Or any reason that makes sense for you!

At retirement, unlike the government sponsored plans, a Private Pension generates tax-free income. (Table 2) And you have access to your money at whatever age you decide. No more being told you have to wait to age 59 1/2. A Private pension is also self-completing. In the event of your death, it would pay a

life insurance death benefit to your survivors. The amount of this benefit will always exceed your account value, substantially so in the early years of the plan. This may allow you to discontinue some of your present life insurance, since this plan includes a death benefit, which might free up additional dollars to deposit for retirement income.

Private pension accounts come in two basic varieties. The first earns dividends or interest. The second allows you to pick from a limited number of underlying mutual funds called subaccount, and your account grows based on the performance of the subaccount you chose. If you're a conservative investor the former is more appropriate; if you're more aggressive, the latter will be more appealing, and is probably more appropriate over the long term.

Since these accounts are offered by insurance companies and include a death benefit they involve passing a physical exam. If this is not practical due to preexisting conditions, you may "borrow" a life. That is, you may have the death benefit cover the life of a family member of business partner. As long as you are the

owner of the account, you still receive all of the tax benefits and still retain all access to the account.

With the passage of the recent tax bill which limits the amounts that you can contribute to your pension and profit sharing plans, as well as imposing even more red tape, these Private Pension accounts make more and more sense. You may have a Private Pension by itself or in addition to your pension or profit sharing plan. This may make a great deal of sense if your deductions were cut under the new tax law.

There are two downsides to a Private Pension account. One of these is that although they do not carry a tax penalty for early withdrawals, they usually do impose a withdrawal penalty for closing the accounts early. That early withdrawal penalty declines each year over ten to fifteen years until it is zero. The early withdrawal penalty is avoidable however. Since it is only imposed for cancellation of the account, it can be avoided by using penalty-free withdrawals from your account in the early years. If you are not committed to keeping the plan in effect for at least ten years you will achieve better results in a comparably performing taxable mutual fund.

The other downside is also related to time. Although these accounts are no-load, their primary advantage is the tax-deferred earnings and tax-free income. However these advantages are only available because they come with a death benefit. The death benefit acts as a drag on earnings and it takes seven to ten years for the tax-deferral to outperform a taxable mutual fund.

The other downside is also related to time. Although these accounts are no-load, their primary advantage is the tax-deferred earnings and tax-free income. However these advantages are only available because they come with a death benefit. The death benefit acts as a drag on earnings and it takes seven to ten years for the tax-deferral to outperform a taxable mutual fund. In short-these accounts

### Comparison of Actual After Tax Income from Pension and Private Pension

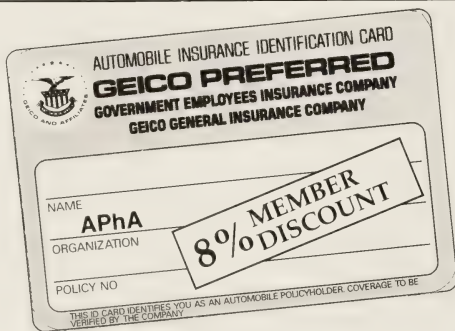
	Pension/Profit Sharing IRA or Keough Account	Private Pension
Annual Gross Deposit	\$ 2,000	\$ 1,440
After Tax Deposit	\$ 1,440	\$ 1,440
Year Ten Total Deposit	\$20,000	\$14,400
Year 10 Account Value	\$28,973	\$19,676
Year 15 Account Value	\$42,571	\$29,573
Annual Pre-tax Income	\$ 4,810	\$ 2,936
Annual After Tax Income	\$ 2,405	\$ 2,936
Fifteen year total Income	\$38,480	\$46,676
Private Pension GAIN		\$ 8,196

Table Two

are most appropriate if you are not going to retire for seven to ten years.

To summarize, Private Pensions make sense if you want to enjoy a

tax-free retirement income, don't want to cover all of your employees, are tired of having to play catch-up with the government every time they change the tax code and want to eliminate red tape. Consider a Private Pension instead of or in addition to your current retirement planning. They make a lot of sense.



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# DRUG PRODUCT QUALITY Review

A PUBLICATION OF THE USP DRUG PRODUCT  
PROBLEM REPORTING PROGRAM

No. 27

## TAKING ACTION THROUGH DPPR

As pharmacists are aware, many of the standards for drug products are set by USP and enforced by the FDA. Products that claim to meet USP specifications but are actually substandard may be subject to recall or enforcement action. Products that are otherwise mislabeled or misbranded may be subject to recall as well.

A "recall" is defined in the *FDA Enforcement Report*\* as a "voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem; others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or field correction of the problem where the product is located." Recalls are classified by the FDA as follows:

Class I—A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

Class II—A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III—A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

### USP REVIEW

The information submitted through the USP Drug Product Problem Reporting Program (DPPR) is shared with the FDA, the pharmaceutical industry, and the Drug Standards and Drug Information Divisions of USP. When reported, product problems can lead to changes in standards, product improvements or, when necessary, product recall. Below are a few examples of DPPR reports that have resulted in product recall.

**CASE NUMBER ONE:** A pharmacist practicing in a California community was filling a prescription for Methocarbamol Tablets. When he opened a sealed bottle of 100 tablets labeled "Methocarbamol 750 mg," he expected to find white tablets. Instead, he found green capsules and a package insert for Indomethacin Capsules 25 mg. The pharmacist reported his findings to DPPR.

Within four days of submitting this report, and as a result of this pharmacist's observations, the firm initiated a Class II recall of the reported lot of Methocarbamol 750 mg. The firm issued the recall upon confirming that at least two bottles from the lot were labeled as Methocarbamol but contained Indomethacin.

**CASE NUMBER TWO:** A hospital pharmacist from Arkansas submitted a DPPR report on Chloral Hydrate Syrup 500 mg packaged in 5-mL unit-dose containers. The pharmacist stated that nurses had expressed concern about the amount of medication in the unit-dose cups, claiming they were overfilled. The pharmacist measured the medication and found that several packages contained 7 or 8 mL, not 5 mL as labeled.

Shortly after this report was submitted, the lot of product reported by this pharmacist was the subject of a Class II nationwide recall. The firm initiated the recall because some of the unit-dose containers were, indeed, found to be overfilled.

**CASE NUMBER THREE:** A pharmacist from a medical center in Ohio submitted to DPPR a sample label of a unit-dose package of plain Promethazine Syrup. The pharmacist pointed out that the product was labeled as an "expectorant and antitussive" and inquired whether the FDA had approved the product to be labeled as such, since Promethazine is usually classified as an antihistaminic. According to the FDA, an investigation of this report resulted in a Class III recall due to the incorrect declaration of the product as an expectorant and antitussive.

While not all DPPR reports lead to immediate dramatic results like the cases described above, these actual examples do demonstrate the effect of a pharmacist's alertness in identifying problems in the marketplace and the impact that may result when problems are reported.

There are several sources of recall information available to the dispensing pharmacist. Among these is the *USP DI® Update*, published monthly to announce revisions and additions to the *USP DI* drug information system. Each *Update* devotes a section to product recalls abstracted from the *FDA Enforcement Report*. In general, the *USP DI* recall section contains all drug and biologic recalls, except those for blood and blood products. Some medical device recalls may be listed if the product is directly related to practice in the ambulatory care setting (e.g., insulin syringes). Recall information in the *Update* is a cumulative 6-month listing allowing pharmacists to track recalls.

Recalls instituted by a firm are not necessarily classified immediately by the FDA, and the recall information does not appear in the *FDA Enforcement Report* until it has been classified. Therefore, for the most current recall information regarding a specific product, USP recommends contacting the firm(s) that are involved.

To report problems with drug products, or for further information, call the USP DPPR Program at 1-800-638-6725.

\*A weekly FDA publication.

# Duty to Warn?

*Yes and No...., But Mostly Yes!*

David B. Brushwood, R.Ph., J.D.



Two recent legal cases illustrate the diverging views courts have of the pharmacy profession and of the responsibilities that should be legally assigned to pharmacists. In both cases, the defendant pharmacist was alleged to have filed the relevant prescription correctly. But also in both cases the pharmacist was alleged to have failed to provide a necessary warning to the patient. At that point the similarity ends, because in one case the pharmacist was held to have a duty to warn, while in the other case the pharmacist was held to have no such duty. An analysis of these two cases can help pharmacists understand the public's expectation of the profession, as reflected in judicial opinions.

In the case of *Walker v. Jack Eckerd Corporation*, No. A93A0691 (Ga. App. 1993) a plaintiff alleged that he was injured from the overuse of Blephamide drops. The plaintiff asserted that he received a PRN prescription for Blephamide, and that the pharmacy dispensed it to him over 15 times in less than one year. The plaintiff asserted that he was diagnosed with glaucoma, which was caused by excessive Blephamide could result in glaucoma.

The court examined that rationale and facts from approximately 25 previous cases from other jurisdictions in which the pharmacist duty to warn issue had been considered. The court then adopted what it referred to as the majority view, that a pharmacist has no duty to warn, because the physician is the person best able to provide warnings to patients about the hazards of drug use. However,

the court noted that Georgia law had changed on January 1, 1993 (the implementation date of the OBRA 90 mandated drug use review rules), and indicated that the rule of this case would have no bearing on actions arising out of occurrences after January 1, 1993. This result was agreed upon by six of the nine judges serving on the appellate panel.

Three judges joined in a dissenting opinion. These judges agreed with the majority that a pharmacist has no duty to warn a patient about all possible adverse effects incident to the use of properly prescribed medications. However, the three judges noted that a pharmacist is more than a clerk who must unquestioningly obey orders of omniscient physicians. The dissenting opinion stated that although the pharmacist owes a duty to the patient beyond just accurately filling a prescription, this does not unduly interject the pharmacist into the physician-patient relationship. The pharmacist should be required, according to the minority opinion, to question a prescription which is erroneous or which is irregular on its face, thereby protecting the patient and the physician from physician errors which the patient could not detect, but which would be readily apparent to a properly trained pharmacist. The dissenting judges would have sent the case to a jury for a determination of whether dispensing Blephamide PRN constitutes such an obvious error that the pharmacist should have contacted the prescribing physician before repeatedly dispensing the medication.



This case may be reviewed by the Supreme Court of Georgia, but that is unlikely. The result stands as a refutation of the pharmacist's duty to warn, pending the filing of a case based on an incident that occurred after January 1, 1993, after which the result would likely be different.

The result was already different in the recently reported Nevada case of *Heredia v. Payless Drug Stores*, 1993 Westlaw 306636 (D.Nev.1993). The plaintiff in this case alleged that he had taken a prescription for Periotic Otic Suspension to the defendant pharmacy, where the prescription was filled without a warning that the use or administration of the product should be discontinued and that the prescribing physician should be promptly contacted in case of symptoms of tympanic membrane rupture. The plaintiff contended that as a result of the drug having been dispensed without appropriate labeling and warning, he suffers from severe and permanent injuries, including brain damage.

The court noted that it is not appropriate for a pharmacist to second guess a physician, unless circumstances indicate that the manner in which a prescription has been issued would be potentially fatal to the patient. The pharmacist does not have a greater duty than that of the physician, nor is the pharmacist an insurer of the safety of dispensed medication. However, it is clear that a pharmacist owes some duty to persons for whom he or she is filling prescriptions. While a generalized duty to warn has been held to be inappropriate in some legal

jurisdictions, generally a pharmacist has a duty to exercise due care in filling prescriptions. At a minimum, a pharmacist must be held to a duty to fill prescriptions as prescribed and properly label them (including the proper warnings), and be alert for plain error. The court thus recognized a duty to warn for pharmacists.

The court concluded that the evidence indicated the pharmacist who dispensed that otic suspension failed to include a written warning to the patient. Therefore, the case was not dismissed, and will proceed to trial, unless it is settled out of court prior to trial.

Taken together these two cases show how the public expectations of pharmacists are changing, and the show the inevitability of a universal duty to warn for pharmacists under the law. While there will be several more years of litigation involving pre-1993 incidents, and those cases may not all recognize a duty to warn, all cases litigated based on events from 1993 and beyond will likely recognize a legal duty for pharmacists to provide warnings to patients. **R**

## About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on legal cases affecting pharmacists and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

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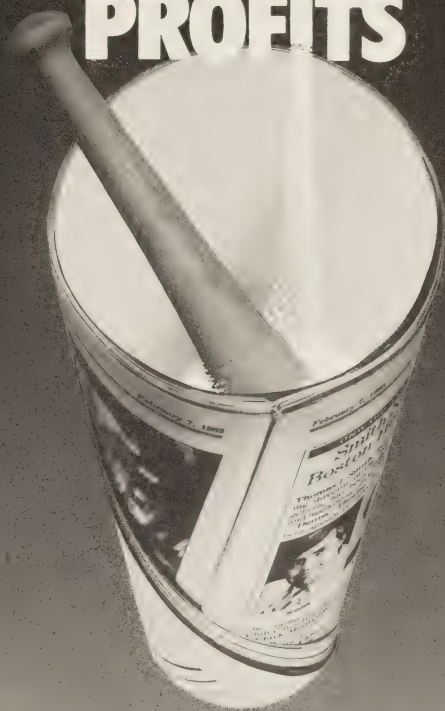
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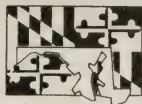
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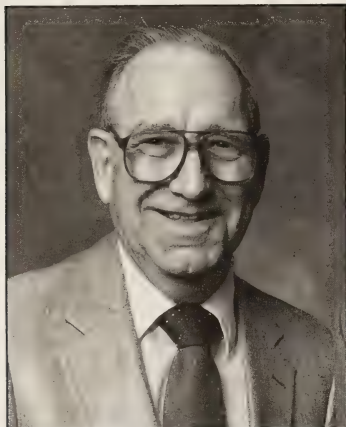


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## Serving the Community

*A Maryland Pharmacist Volunteers in South America*

*James M. Rutten, P.D.*



In my capacity as a pharmacist I was privileged during this past summer to participate in a medical mission trip to the rural Andean area of Bolivia in South America. This trip allowed me to use my professional knowledge to assist in upgrading and reorganizing two small pharmacies in the hospitals in Mallico Rancho and Sipe Sipe, and also to have a marvelous vacation in a very interesting part of the world that I would not otherwise have visited.

The trip was sponsored jointly by UMCOR (United Methodist Commission on Relief) and the ARHC (Andes Rural Health Care). ARHC is a program developed by Dr. Henry Perry. In 1969, while still a student at Duke University, Perry traveled to Bolivia as a part of a student work-study team. Because of the enormous unmet medical needs he saw there, he felt called to respond. After completing medical school and graduate studies, Dr. Perry returned to Bolivia. From 1981 to 1984 he worked to establish ARHC's initial project in Carabuco. Duke University served as a sponsor of this original effort and additional financial support was provided by individuals, churches and foundation grants.

The work continues, and several teams go into this area each year. Our work team consisted of sixteen people, twelve from the Rockville-Frederick, Maryland area, three from North Carolina and one from Minnesota. There were 11 women and five men on the team.

All of the team members met at the airport in Miami and then flew overnight to LaPaz, Bolivia and went

from there to Cochabamba.

We worked out of six bed hospital in a rural community called Mallico Rancho, located about twenty five miles from there to Cochabamba. The hospital, located in a fertile valley in the foot hills of the Andes at an altitude of 8,500 feet, provides basic health care to the economically disadvantaged residents - mostly Amaya and Quecha Indians, descendants of the Inca.

Mallico Rancho is a group of eleven agricultural communities with a population of about 6000 people. The ARHC works through a bolivian organization known as APSAR (the Association of Rural Health Programs). The ARHC/ASPAR has spent the last five years addressing the community needs in the areas of Medicine, Education, Economics, Agricultural, Water, Sanitation and Transportation.

What did I do during my ten days in Bolivia? We had taken sixteen cartons of drugs with us -- all of which had been donated by U.S. pharmaceutical companies. I rearranged the hospital pharmacies in Mallico Rancho and Sipe Sipe, Aligning items in a therapeutic sequence and worked with the physician assigned to these hospitals.

I was invited to make home visits with the Care Giver, who worked out of the local hospital, when she visited the local population in their homes. These visits were extremely interesting to me to see how the people lived and the type of medical care available to them. The Medical Care-Giver followed the health of children from birth to about five years





Andes Mountains of South America  
surrounding the farming area of Mallco Rancho

of age. They checked the weight and height of the children to determine whether or not they met a preestablished standard. They gave immunizations against Polio, DPT, and Measles and instructed the mother on the importance for boiling their drinking water and if diarrhea occurred, how to treat. Each home was visited one or two times in a six month period. All other illnesses were referred to the local hospital for treatment.

The trip was not all work. On two evenings we had the opportunity to attend concerts of Bolivian music staged for the team and to mingle with members of the local hospital staff. The music was different and very enjoyable. The people very outgoing and friendly. On one weekend day, we visited the ruins of an ancient civilization and the Temple ruins of Tiwanaka near Lake Titicac. The following day was a day of shopping in LaPaz the capitol of Bolivia where almost everything is sold by street vendors. In one area called "The Market" one could buy items of clothing, food, and precious stones. It paid to be a "haggler". We also visited several beautiful churches built by the Spanish Missionaries.

We departed from LaPaz, a modern city with many high rise buildings, tourist attractions and the comforts of living that we have in the USA. LaPaz is located at an altitude of 13,000 feet and it takes some time to become accustomed to this height.

The airport is located on the Alto Plano which above the city of LaPaz. Because of the thin air, the aircraft could not take off with a full load of fuel and flew south to an airport at a lower altitude to finish fueling before heading north.

I found this work mission trip to be a very rewarding and interesting experience. Anyone desiring to become a member of a future Bolivian Medical team should contact the ARHC International office located at 518 Lakeshore Drive, Lake Junaluska, NC 28745. **R**



The hospital and water tower at Hospital Mallco Rancho.

# Catch the Winning Spirit

Highlights from the 112th Annual MPhA Convention



MPP Executive Director Jim Miller and EPIC Network's Pat Berryman strategize during the Trade Exposition



MPhA First Lady Barbara Schiff, caught in the act of betting her husband's dues for the year, at the "Night at the Races" reception



MPhA Treasurer Ron Sanford, trying to figure out why nobody wants six hour business sessions for the House of Delegates



Thanks go to Marion Merrell Dow folks for sponsoring lunch in the Trade Exposition on Monday



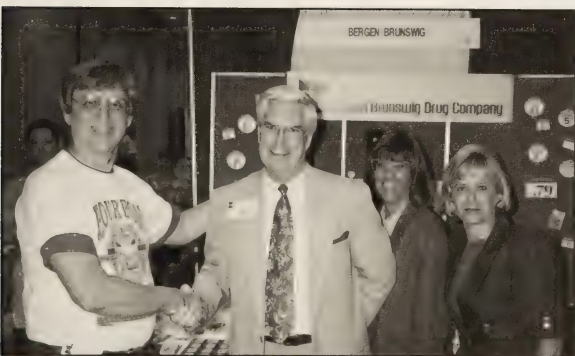
Legislative Committee member Susan Redmer and Vice-Speaker Alisa Billington count their "track" winnings



Outgoing President Nick Lykos hands over command of the MPhA to Incoming President Howard Schiff



MPhA Counsel Joseph Kaufman reports on the legal issues facing pharmacy during the House of Delegates meeting



Maryland Board of Pharmacy Commissioner Bob Kabik welcomes the representatives of Bergen Brunswig



Big winner Catherine Marsiglia and dad Phil break the bank with winning bets during the races



Outgoing Honorary President Mark Golibart without donuts



# Continuing Education

## Continuing Education Quiz

October 1993 -- Communication Barriers

This month's questions are taken from articles appearing in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by March 31, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

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1. According to the ADA, disabled persons include:
  - a. the physically impaired
  - b. the mentally impaired
  - c. a only
  - d. a and b
2. Aphasic patients may not be able to:
  - a. read patient information leaflets
  - b. hear oral instructions
  - c. verbally ask questions
  - d. taste bitter medicine
3. The SMOG Conversion grade level of the first page only of *Dickinson's Pharmacy* is:
  - a. grade 10
  - b. grade 12
  - c. grade 14
  - d. grade 16
4. If this article page was rewritten for the reading impaired, the SMOG Conversion grade level should be:
  - a. grade 4
  - b. grade 5
  - c. grade 6
  - d. grade 7
5. According to Jim Dickinson, which of the following should oversee mail-order pharmacy practices:
  - a. State Boards of Pharmacy
  - b. Food and Drug Administration
  - c. the NARD/NACDS Coalition
  - d. State Departments of Health
6. Investigator Hammel reports that the street value of hydromorphone can be as high as:
  - a. \$ 55 per tablet
  - b. \$ 35 per tablet
  - c. \$ 15 per tablet
  - d. \$ 5 per tablet
7. Pharmacists who doubt the legitimacy of a prescription should always contact the prescriber.
  - a. true
  - b. false
8. Of the three classes of FDA recalls, which class represents the drugs with the greatest threat to patients?
  - a. Class I
  - b. Class II
  - c. Class III
  - d. Class IV
9. In *Walker v. Jack Eckerd Corporation*, the court ruled that the pharmacist...
  - a. had a duty to warn the patient
  - b. had no duty to warn the patient
  - c. had a duty to warn the patient before and after January 1, 1993
  - d. had no duty to warn the patient before and after January 1, 1993
10. In *Heredia v. Payless Drug Stores*, the court ruled that the pharmacist...
  - a. had a duty to warn the patient
  - b. had no duty to warn the patient
  - c. had a duty to warn the patient before and after January 1, 1993
  - d. had a duty to warn the patient before and after January 1, 1993

# Biotechnology Investing

## Is it for you?

Clay McNally, *The Equitable*

Regardless of a country's economic climate, the need for medical products and services appears to be unaffected. This is evident by the fact that health care costs in the United States have continuously increased despite the economy's slow growth. Currently health care expenditures in the U.S. represent 14% of the GDP (Gross Domestic Product), the highest for all industrialized nations.

In 1991, the amount of money invested in the world's health care industry's market was close to \$600 billion.<sup>1</sup> This ranks health care fourth compared to the stock markets of the world's industrialized nations. It surpasses all but the United States, Japan, and the United Kingdom in size.

One major factor contributing to the increase in health care expenditures is the United States growing elderly populations, and their demand on health care. It is estimated that a person over the age of 75 spends ten times as much money on health care as a person between the ages of 20 and 50.<sup>2</sup> Other factors contributing to the increasing costs include technological advancements such neonatal intensive care units, transplants and the new biopharmaceuticals.

Biopharmaceuticals have not only caught the attention of health care providers and managers but also investors. Despite recent down turns in the biotech industry's performance, this volatile sector outpaced the average common stock mutual fund over five years from 1988 to 1992 according to Morningstar (an independent mutual fund rating service). Amgen, one of the most successful biotech companies, the developer of Epogen was selling at \$7 a share in 1989 by the end of 1991 the price had reached \$76, at the close of the market on September 16, 1993 Epogen was selling at \$38.50. Today, there are some 225 biotech companies worldwide which are publicly traded, and several hundred that are privately held.

Biotech companies are considered fairly risky investments because they are based more on product promise than product performance. Similar to conventional pharmaceuticals, licensure is dependent upon strict production specifications. This often requires the company to commit funds to facility production before its product is even in Phase III clinical trials. If the biopharmaceuticals does not obtain FDA approval this

commitment may mean financial ruin for the company. Even if the product makes it through Phase III clinical trials and receives FDA approval, the company may find itself in court defending its ownership against a competing biotech company which claims it developed the product first. Compared to conventional drugs, patents for biopharmaceuticals are more often contested. On the other hand, evidence suggests that the failure rates for new biopharmaceuticals are lower than that of conventional pharmaceuticals.<sup>3</sup> In other words, the proportion of abandoned drugs, those which do not make it through clinical trials, is lower for biotech companies resulting in lower costs.

To fund the high costs of production many biotech companies depend on eager investors. When cash was low they would simply issue more shares. However, because of the recent failures of many small "start-up" companies this market has all but dried up. According to analysts this has forced many companies to enter into mergers, joint ventures or licensing agreements with pharmaceutical manufacturers.<sup>4</sup> Pharmaceutical manufacturers, on the other hand, with their strong cash flows appear to be just as eager to enter into these new ventures for their own reasons.

### World Market Capitalizations



IFC and Computat

Pharmaceutical stock which rose 1,100% between 1978 to 1991 (an annual total return of 20%) are now projected to only gain between 3% to 5% over the next five years.<sup>5</sup> This projected low rate of growth is contributed to the fact that many major pharmaceutical manufacturers are expected to lose patent protection on their primary money makers over the next several years. Many third party payers are requiring generic substitution when possible or offer monetary incentives to patients to use generics. Price pressures from the more regulated foreign markets such as Japan, Britain and Germany have all contributed to the recent shift away from pharmaceutical stocks. Others have blamed the Clinton administration and the uncertainty over health care reform.<sup>5</sup> Consequently, pharmaceutical manufacturers have looked to new markets such as biotechnology.

Several of these mergers include Schering-Plough which has entered in a licensing agreement with Biogen to market alpha interferon. In addition, there is the joint venture between Eli Lilly and Genetech to manufacture recombinant insulin. Recently, Roche Holdings, the parent company of Hoffman-La Roche acquired 60% of Genetech, while American Home Products acquired 67% of Genetics Institute. All of these biotech companies have produced products which have received FDA approval.

So where should an individual interested in the biotech market invest? According to Peter Lynch, the previous manager of the Magellan Fund, you have two choices.<sup>4</sup> You can invest in pharmaceutical manufacturers which have joint ventures with biotech companies. However, they too may be too risky for your blood. Or you can invest in mutual funds, letting the professional money managers pick the investments. One such expert is Sandra Panem, who manages the Oppenheimer Global Bio-Tech fund. In 1991, Oppenheimer Global Bio-Tech was the #1 mutual fund and attained a rate of return of better than 120%. Since inception through August 1993 Global Bio-Tech has averaged 13.5%. Ms. Panem has a Ph.D. in microbiology and has experience in the economics of biotechnology. It appears essential for these fund managers to have dual areas of expertise in science and money management. Biotechnology not only has great potential for earnings but is also quite volatile and not for every investor.

Before the decision is made to invest in biotechnology or any other industry, your personal or business goals need to be established. This goal setting and evaluation process should include but not be limited to: length of time to keep the investment, flexibility of contributing additional monies, timing in the market, personal comfort level with the volatility of the product, and the overall mix of your existing investment portfolio. One of the most important rules to remember is that past performance of a stock or mutual fund is no guarantee of future results. The assistance of an experienced professional is most beneficial when you are considering any changes in your business or personal financial plans. **R**

## About the Author

Clay McNally is an Agent/Registered Representative of The Equitable Life Assurance Society, 100 Light Street, Suite 1400 Baltimore, Maryland 21202.

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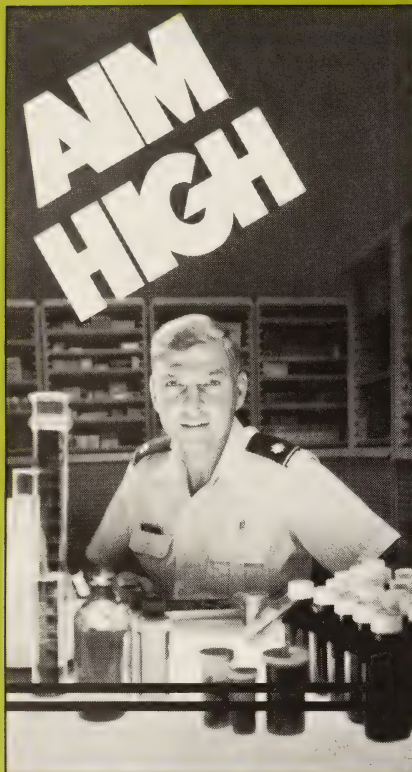
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# *The Maryland Pharmacist*

VOL. 69

NOVEMBER, 1993

NO. 11



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

November 1993

Volume 69

Number 11

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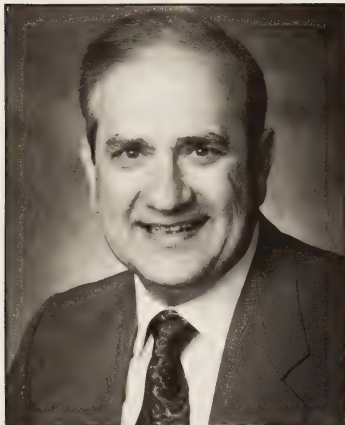
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# President's Commentary

*Howard Schiff, P.D.*



After years of investigation the Federal Trade Commission finally issued a complaint against the MPhA and the Baltimore Metropolitan Pharmacists Association charging that the two Associations conspired to cause an illegal boycott of the Baltimore City employee's health plan in 1988.

The whole thing really ticks me off,

I never could believe that the "suits" in Washington would take action against *us*. We were two small Associations fighting against giant insurance company Prudential -- David versus Goliath. After all, the government is supposed to help small businesses. Shows you how naive I was. The FTC and HCFA throughout the Reagan and Bush years were constantly treating community pharmacy -- especially independents -- as an anachronism, some artifact from a bygone year that did not belong in their vision of health care in the 80's and 90's.

Even when the FTC investigation was completed their only evidence of substance against the two Associations was a list of pharmacies that were choosing to refuse the Prudential contract. This list was compiled by MPhA and BMPA simply because City officials asked us to so that they could assess the extent of damage wreaked by Prudential. There was no boycott of the Prudential program. There was no attempt to secretly undermine the City's prescription program. There was no intent to do anything but allow the City to resolve a problem with one of its subcontractors. Of course the FTC never mentioned that there was absolutely no evidence that any City employee was denied medication or that any prescription went unfilled, despite Prudential's unfair actions. Goliath won this battle.

Looking back five years at this issue, I have more unanswered questions. Were we wrong to fight against a Prudential's unilateral reduction in reimbursement by going to City officials? Should we have just turned a blind eye to Prudential's self-serving decision? Was Prudential's decision due to overpayment to pharmacies or to their lack of control over costs? Could it be that Prudential just underbid the contract in hopes of eliminating Blue Cross as a competitor for the City's business?

There are now 30 percent fewer independent pharmacies in Maryland this year than there was only three years ago. This trend is also spreading to major chain pharmacies as many stores are being closed or consolidated. Reduced third-party reimbursement had to play a major role in the demise of these pharmacies. With health care reform on its way, will the remaining community pharmacies soon join the ranks of "used-to-be-be-a-drugstore-here"? Is not pharmacy's scramble to focus on "niche" practices and pharmaceutical care our way of saying that prescriptions alone cannot support the traditional community pharmacy?

Stay tuned. We may not prosper during the on coming years but it sure as hell will be interesting.

**R**



## The American Health Security Act

*President Clinton's Anticipated Health Care Reform Program*

*William M. Hermelin, Director, Government Affairs, APHA*



In a September 22, 1993 televised address to a joint session of Congress, President Clinton outlined a sweeping proposal to reform the nation's health care system, guaranteeing a standardized package of health benefits for all Americans and changing the way most citizens will pay for and receive their medical services. This health reform program is entitled the American Health Security Act.

A 239-page preliminary draft providing specific details of Clinton's proposal was distributed several weeks before the President's planned speech. In the document, the President presents the main elements of the initiative -- how the reformed health care system will be structured, how it will work, and what responsibilities the federal and state governments will have in implementing the new system.

The plan also includes specific provisions in many key areas of concern to pharmacy. Most significantly, outpatient prescription drugs are included as part of the standard benefits package to be offered by all health plans. The proposal also includes a new Medicare outpatient prescription drug benefit.

According to the White House, the draft is a working document that will be revised to reflect refinements of the policy as it is reviewed by Congress. The President is expected to submit the proposal as legislation in November. Several other plans, including Senate and House Republican proposals, a market-based managed competition proposal developed by the Conservative Democratic

Forum, and a federal single-payor plan already introduced in the House by liberal Democrats, will also be considered by Congress.

Clinton's proposal blends market forces with a strong government role. It confirms many of the features that have been previously disclosed to pharmacy by administration officials and reported in consumer and trade publications.

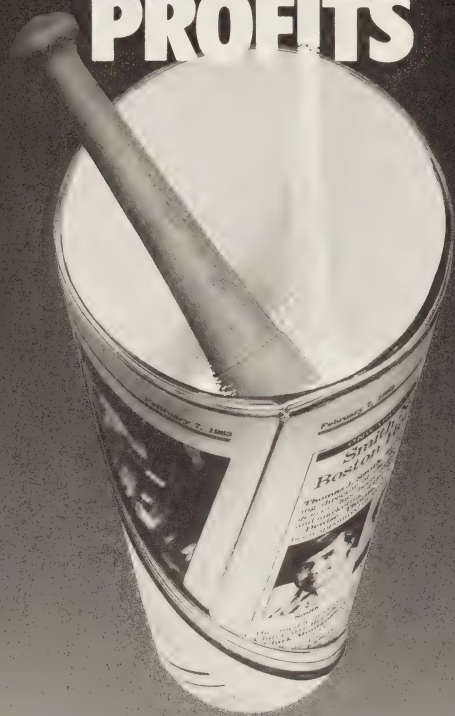
Major features of Clinton's proposed American Health Security Act include:

**Universal Access** All Americans are guaranteed access to health services in a nationally defined, comprehensive package of benefits with no lifetime limits on coverage. All employers would be responsible for contributing approximately 80 percent of the costs of basic health coverage for their employees. Employees would be required to pay 20 percent.

**Guaranteed National Benefit Package.** In addition to hospital and emergency services, the national standard package includes: outpatient prescription drugs, the services of physicians and other health professionals, clinical preventive services, hospice care, home health care, outpatient laboratory and diagnostic services, and durable medical equipment including prosthetic and orthotic services.

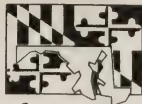
**State-controlled Regional Health Alliances.** Health alliances, set up by the states, would be responsible for encouraging the delivery of cost-effective, high-quality health care within a specified geographical area. Individuals would receive their health care benefits as enrollees in these

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## The Clinton Health Reform Plan and Pharmacy

### Issue

#### **Provider Networks Freedom of Choice**

### What the Proposal Says

Health plans can:

- Limit the number and type of health care providers who participate in the plan
- require enrollees to obtain health services from participating providers or from plan authorized providers
- establish different payment plans for participating health providers and providers outside the plan
- use single source suppliers for pharmacy (a single chain, a single PSAO or buying cooperative or a single mail-order system)

State freedom of choice laws would be preempted (except for services provided under a fee-for-service plan).

#### **Manufacturer Cost Containment**

The National Health Board could "make public declarations regarding the reasonableness of launch prices." Initially, such determination would be based on a comparison of prices for therapeutically-similar drugs in the U.S. and in seven other industrialized countries.

In the universal benefits package, there is a \$5 prescription drug co-pay regardless of whether the drug is single or multi-source.

Under Medicare, manufacturers would be required to pay a rebate similar to the one established for Medicaid by OBRA '90. The Health and Human Services Secretary is authorized to negotiate a "special rebate" for those new drugs determined to be excessively or inappropriately priced. Only generic drugs are covered unless the physician indicates that a brand-name drug is medically necessary. Physicians may have to obtain prior approval before prescribing specific brand-name drugs if a generic substitute is available. Both physicians and pharmacists may be required to obtain prior approval for certain medications that the Secretary determines "are not cost effective," or are subject to clinical misuse or inappropriate use.

alliances. All residents would enroll in one of the several health plans that will be offered within the region by the alliance. The alliances would be responsible for approving competing health plans, bargaining with them over price, and monitoring and collecting data about their quality. Employers with more than 5,000 workers would have the option of forming their own corporate alliances or of joining a regional alliance.

*Health Plans.* The health plans -- networks of pharmacists, doctors, hospitals, and other providers -- would contract with the health alliances to provide the standard package of benefits. Consumers would have a choice of plans: a health maintenance organization option; a more traditional fee-for-service option that allows unrestricted provider choice; and a combination of the two options that would allow some choice of provider. Health plans within a region would promote their services and compete for members.

*National Health Board.* The President's plan would establish an independent federal board composed of seven health care experts appointed by the President and approved by the Senate. The National Health Board would have the power to set uniform national standards for benefits, quality, and access to care. It would be responsible for overseeing the establishment and administration of the new health system by the states. The Board would set an overall national budget for health care spending and establish individual budgets for the health alliances, allowing for regional variations.

Clinton's proposal would retain the Medicare program, while giving consumers age 65 and over the options of participating in one of the regional health alliances if they prefer. Federal employees and Medicaid beneficiaries would be folded into the universal access program. The Department of Veterans Affairs would be able to organize its existing health centers and hospitals into health plans similar

to those serving the general public.

Implementation of the President's plan is anticipated to cost an estimated \$700 billion over the next five years. Its costs would be funded partly through "sin" taxes, further restraints on Medicare provider expenditures, and from other sources, and its growth in total expenditures would be based on the Consumer Price Index.

### Pharmacy-Related Provisions

Clinton's proposal to restructure the country's health care system covers several key areas of concern for pharmacists. It will have a dramatic impact on their role as practitioners and health care providers. Many of these areas have been the focus of pharmacy's lobbying activities during the past year and have formed the basis for the principles and positions advocated by the Coalition for Consumer Access for Pharmaceutical Care, of which APhA is a founding member.

Indications of how the administration's plan may address key areas of interest to pharmacists are listed below.

*Pharmaceutical and related benefits.* Outpatient prescription drugs and other pharmacy-related services are included in the guaranteed national benefit package. There are no limitations on the frequency or quantity of outpatient prescription drugs. The administration's proposal allows health plans to establish formularies, drug utilization review, generic substitution, and mail order programs.

Other services listed in the standard benefits package that relate to the provision of pharmacy services are: clinical preventive services (which include certain immunizations, hematocrit tests, and cholesterol screening); hospice care; home health care; durable medical equipment, prosthetic and orthotic devices; and outpatient lab and diagnostic services.

*Provider Networks/Freedom of Choice.* Health plans would be allowed to limit the number and type of

## The Clinton Health Reform Plan and Pharmacy

### Issue

#### **Coverage for Pharmaceuticals**

### What the Proposal Says

All approved health plans would have a comprehensive benefits package that includes: outpatient prescription drugs and biologicals; outpatient lab and diagnostic services; DME, prosthetic and orthotic devices; hospice care; home health care (including prescribed home infusion therapy, outpatient prescription drugs and biologicals). There is no specific mention of pharmacists' services.

Under Medicare, an outpatient prescription drug benefit would be implemented by July 1, 1996. There would be a \$250 deductible, a 20% copay and an annual out-of-pocket limit of \$1,000. All drugs (including home IV drugs) would be covered for their medically accepted indications.

Physicians or pharmacists may have to get prior approval for certain drugs subject to clinical misuse, inappropriate use or because the Secretary of Health and Human Services determines they are not cost-effective. The Medicare drug benefit would include a DUR program similar to OBRA '90's, including pharmacist counseling.

Under Medicare, reimbursement for brand-name drugs would be at the lower of the 90th percentile of actual charges in a previous period or the Estimated Acquisition Cost (EAC) plus a dispensing fee. For generics, the level will be the lower of the pharmacist's actual charge or the median of all generic prices (times the number of units dispensed) plus a dispensing fee. For participating pharmacies, the dispensing fee is \$5, indexed to the CPI. For non-participating pharmacies, the fee is \$3.

#### **Anti-Trust**

The McCarran-Ferguson health insurers' exemption to antitrust legislation will be repealed.

Federal guidelines will be issued to permit provider networks authority to collaborate to negotiate effectively with health plans.

participating providers. The plans could also "require participants to obtain health services from participating providers or from providers authorized by the health plan." They are also allowed "to establish different payment rates for participating health providers and providers outside the plan" and "to use single-source suppliers for pharmacy, medical equipment, and other health products and services." State freedom-of-choice laws would be pre-empted by the requirements.

*Equal Access to Pharmaceutical Prices.* To participate in Medicare and Medicaid, manufacturers will have to offer "discounts to all purchasers of pharmaceuticals on equal terms." Drug companies would still be allowed to offer "differential discounts" based on volume buying or other economic advantages they realize. They would not be allowed to provide discounts based solely on the class of trade to which a drug purchaser belongs.

*Manufacturer Cost Containment.* While the President's plan does not impose direct price controls on drugs, it includes several provisions intended to restrain growth in pharmaceutical pricing. The National Health Board could "make public declarations regarding the reasonableness of launch prices." Initially, the Board would determine if prices are reasonable by comparing the prices of therapeutically-similar drugs in the United States and seven other industrialized countries. Under the new Medicare prescription drug program described below, manufacturers would be required to pay a rebate similar to the one established for Medicaid by OBRA '90. Also under Medicare, the Secretary of the Department of Health and Human Services can negotiate a "special rebate" for new drugs that are deemed to be excessively or inappropriately priced.

#### **Medicare Prescription Benefit**

A new outpatient prescription drug

## **The Clinton Health Reform Plan and Pharmacy**

### Issue

#### **Discriminatory Pricing**

### What the Proposal Says

As a condition of participation in Medicare and Medicaid, manufacturers will have to offer "discounts to all purchasers of pharmaceuticals on equal terms." Price differentials are permitted where they are based on economic advantages realized by manufacturers. Manufacturers would be precluded from providing discounts to purchasers based solely on the class of trade to which the purchaser belongs.

#### **Information Systems**

With state and private entities, the National Health Board will develop uniform national standards for administrative, clinical, financial and health care related information. However, there will not be a full-scale computerized record. "Local solutions to local needs will be fostered." Community based health information systems will be designed to improve quality and reduce costs by minimizing duplicate procedures, tests, and adverse drug reactions. The NCPDP universal drug claim form will be used by pharmacies seeking reimbursement.

benefit, modeled after the program in the Medicare Catastrophic Coverage Act of 1988, would go into effect by July 1, 1996. In addition to prescription drugs, biological products, and insulin, the plan covers home intravenous drugs and immunosuppressive drugs. Some drugs may not be covered, such as those used for cosmetic purposes, although benzodiazepines and barbiturates are explicitly included.

Beneficiaries would have to meet a deductible of \$250 a year and thereafter pay 20 percent of the cost of each prescription with an annual coverage limit of \$1,000.

Reimbursement for brand name drugs is the lower of the 90th percentile of actual charges in a previous period or the estimated acquisition cost plus a dispensing fee. For generic drugs, Medicare pays the

lower of the pharmacist's actual charge or the median of all generic prices plus a dispensing fee. For participating pharmacies, the dispensing fee is \$5, indexed to the Consumer Price Index.

Under Clinton's proposal, only generic drugs would be covered unless the physician says that a brand-name product is necessary. In some cases, physicians may have to obtain prior approval before prescribing brand-name drugs instead of generics. Prior approval may also be required for certain medications that "are not cost effective," or are subject to clinical misuse or inappropriate use. In addition, the President's plan calls for a Medicare drug utilization review program similar to the one established in OBRA '90 for Medicaid patients.



## Other Provisions

**Antitrust Reform.** Clinton's proposal acknowledges that networks of pharmacists and other providers need some protection to negotiate effectively with health plans. To do this, the plan repeals the health insurers' exemption under the McCarran-Ferguson antitrust law, eliminating the ability of health plans to collectively determine the rates they charge. In addition, federal guidelines will be issued that give provider networks authority to collaborate so they can effectively negotiate with health plans.

**Integrated Information Systems.** The plan calls for the National Health Board, with state and private entities, to develop uniform national standards for administrative, clinical, financial, and other health care

related information. The plan states that a full-scale computerized patient record will not be developed, but that "local solutions to local needs will be fostered." Community-based health information systems will be designed to improve quality and reduce cost by minimizing duplicate procedures, tests, and adverse drug interactions. The plan also requires pharmacies that seek reimbursement to adopt the Universal Drug Claim Form by January 1, 1995.

Clinton's proposal stresses the importance of public health information and education programs -- areas that could give pharmacists more opportunity to function as integrated members of the health care team and to expand their roles as primary care providers. Priority areas mentioned in the plan include immunization,

HIV/AIDS education, diabetes education and control program, smoking cessation, and family planning. A new health care initiative to be developed under the plan, the designation of essential community providers, could also open the doors to pharmacists as front-line health care providers. **R**

## About the Author

William M. Hermelin is Director of Government Affairs for the American Pharmaceutical Association, 2215 Constitution Avenue, NW, Washington, DC 20037.

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## 10 Ways To Kill Your Profession

Andrea Graham

Pharmacists don't have a lot to celebrate these days. The uncertain future of health-care reform, expansion of mail order pharmacy, prevalence of discriminatory pricing, administrative demands of third parties, their encroachment on clinical matters and generally bad press about the cost of drugs have cast a pallor over the pharmacy community.

Pharmacists have good reason to complain -- nearly all must work faster, counsel more and negotiate to the bone for modest dispensing fees that continue in a downward spiral.

However, some in the profession, suffering from battle fatigue or flawed logic, think these are legitimate reasons for lowering their level of professional service. It's easy to forget that every corporate CEO and benefits manager, every legislator, even every third-party administrator is some pharmacist's patient. The impressions that can be left "in the wink of an eye" will, for better or worse, influence the climate for all pharmacists.

The message is clear -- pharmacists should never lower their level of professional conduct.

It's generally agreed that most of our problems stem from a common lack of understanding about what pharmacists do. This is made worse by the commercialization of pharmacy, which emphasizes every easily measurable aspect -- like price -- and overlooks the pharmacist's role as the bulwark of the patient's health.

It is no secret that in many managed care organizations, large patient loads have greatly limited the amount of time a physician or

pharmacist can spend with each patient. That this makes the pharmacist's role even more critical in monitoring drug therapy seems lost on the "powers that be."

While no one disputes that the problems and players are different from 10 years ago, the solution probably hasn't changed: demonstrate to all pharmacy's constituencies -- patients, payers, employers, the government and anyone else who will listen -- the contribution pharmacists make to the patient's health.

Such demonstrations can't be accomplished solely behind the counter.

However, if you think things can only get worse and you want to contribute directly to the patients' lack of understanding about what pharmacists actually do, here are 10 handy and surefire ways to undermine your own value as professionals.

### **Emphasize counting abilities above all else.**

Since people think pharmacists primarily count pills, don't do anything to disappoint them or change their impression.

Benita Council, a community pharmacy owner in Los Angeles, explains how easy it is to send that message by saying, "It'll be ready in one minute -- all I have to do is count 'em out!" That way, patients will have minimal expectations and will yell only when you've shorted them a pill or two.

However, Council points out that

the real solution to changing this misconception is "to counsel early, often and on a level that patients can understand."

### **Treat your patients like customers.**

It has been a non-negotiable point of protocol in pharmacy associations to refer to the people pharmacists fill prescriptions for as "patients" rather than customers. However, most people still do a double-take when they hear themselves addressed as such.

This is particularly true if the patient's pharmacist does nothing to discourage the impression that a prescription is just another "commodity product" like detergent or tennis balls. Pharmacists should not continue to conceal those aspects of the profession which require a graduate degree.

The other way to undermine pharmacy is to treat your patients like walking cash registers, giving them the cold shoulder when they decline to purchase the appropriate accompaniments to their allergy prescription or let slip that they've gone to mail order for their blood pressure medicine.

### **Always remember that "listening" isn't in your job description.**

Yes, pharmacists are expected to gather certain information about the patient, especially as it might apply to allergies or other medications and

OTC products that could produce a drug interaction. But it's another thing to have to listen to someone prattle on, especially when your mind might be elsewhere.

Listening not only will give you some insight how to help, but could even put you in that powerful and crucial position of saving the patient's life by picking up that thread of information you or some other qualified professional really needs to know.

**Never counsel or give advice -- it might get you into trouble.** You can easily discourage patients from forcing

you to express an opinion by making them do all the work. Here are some catch phrases; "Sign here if you don't need to talk with the pharmacist," "There's nothing you need to know about this medicine, is there?" "You've taken this before, right?" "The directions are on the package insert."

Even if you don't say anything, having a blank look when a patient asks a question will usually discourage further inquiries. Besides, if you recommend a product or solution that doesn't work, they'll just blame you anyway. So let them take responsibility for making their own mistakes.

Marilyn Friedberg, a chain store pharmacist in Los Angeles, explains, "While the right OTC product can sometimes solve the patient's problem quickly without medical intervention, the wrong one can do nothing at all, or worse, it can get them into trouble.

Good pharmacists share their knowledge freely, and usually find their expertise much appreciated."

**Don't waste time developing personal relationships with your patients.** When

you're in production mode, small talk only slows you down. Besides, your patients aren't coming to the pharmacy for you, no matter how friendly you are or how well you serve them. They are certain to defect down the street to save a quarter.

Ruth Smarinsky, a community pharmacist in Los Angeles, suggests that the best way to send your patients away is to never talk to them "unless it's to yell at them." She quickly adds, however, "letting your patients know you care about them is the real secret to loyalty" that will keep patients coming back, even under payer pressure.

Friedberg interjects, "Staying in touch with the human aspect of our job makes being a pharmacist easier and more rewarding. After all, what goes on between patient and pharmacist should be a dialogue, not a monologue."

**Operate the pharmacy for the convenience of management.** This is

a very effective way to convince people that mail order is a preferable alternative. If you want an example of how another industry convinced consumers they didn't want personal attention, look at banking. Banks, like

pharmacies, once built their fortunes on personal attention and treating each client's problem individually. Now they compete on ATM networks, free checks and a micro-percent interest differential.

**Always defer to the doctor.**

Don't let the patient know how much you know. This a corollary to the point about giving

advice.

Since it's usually a hassle dealing with doctors anyway, go ahead and let them make all the decisions. If they make a mistake, send the patient back to their office rather than resolving it by phone. If you detect a potential drug interaction, conceal your involvement from the patient at all costs.

Gary Dreyfus, a community pharmacy owner in Laguna Niguel, points out, "Often, all the patient sees is the finished product: the filled prescription. So how are they to know and appreciate that we've possibly saved them from suffering, contributed significantly to the improvement of their health -- unless we get out into the community and educate them about what we do?"

**Stay behind the counter.** Keep your

eyes to the wall. If you want pharmacy to go down the tubes, it is very important to stay behind the counter at all times and never let patients see what you do.





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**9** Repeat three times a day, "It's not my job, it's not my job, it's not my job." The more you volunteer advice and personal service, the more people will expect. So start each day avowing you will do only the minimum necessary to keep your job. If you abdicate most responsibilities altogether, it's easy to discourage demands by being as unhelpful as possible.

**10** **Treat your managed care patients like second-class citizens.** Establish a caste system in your pharmacy by singling out the undesirable (that is, low-profit) patients. You might even consider putting a day-glow sticker on their patient records to make sure they don't get more time and attention than they deserve. Save your energy and enthusiasm for the ones who pay cash.

If you recognize yourself or someone you know in this article, take stock of what's at stake for pharmacists. While no one will deny that pharmacists are over-worked and under-loved, the future isn't entirely out of control. Be front and center about what pharmacists do, and then do it as well as you possibly can. This way, there is still the chance to shape the future. **R**

## About the Author

Andrea Graham is a principal of Graham, Silberg, Sugarman Inc. Her firm specializes in marketing for associations and health care providers. This article originally appeared in the May 1993 issue of *California Pharmacist* and is reprinted with permission.

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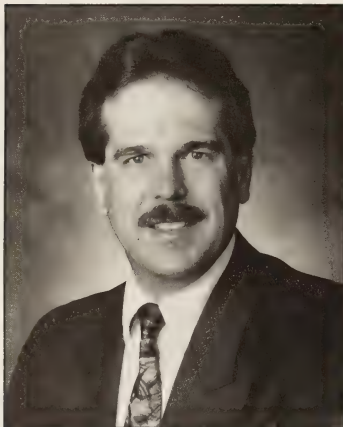
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# Pharmacy and the Standard Benefits Task Force

*MPhA and MACDS Join Pharmacy Manufacturers*

*Ernest Testerman, P.D., Chairman, MPhA Legislative Committee*



A major part of Maryland's health care reform initiative is the creation of a standard benefits package. That package will be offered by all carriers, insurers, preferred provider organizations (PPO), or health maintenance organizations (HMO), that sell health coverage to the small employer group market. Small employers are defined as those who have between two and 50 employees.

Maryland's Health Care Access and Cost Commission (HCACC) is charged with designing the standard benefits package. A task force of HCACC members and volunteers from the insurance and business community have been working on the design of the package since summer. In September, MPhA, the University of Maryland School of Pharmacy, the Maryland Association of Chain Drug Stores, and the Pharmaceutical Manufacturers Association testified before the Standard Benefits Task Force.

MPhA's testimony had three messages: pharmaceuticals and pharmacy services must be part of a standard benefits package; there must be a sharing of risk between the benefit provider and the beneficiary -- in this case the employee; and an explanation of the good and bad aspects of current third-party prescription programs operating in Maryland. Our comments were accepted with great interest by the Task Force and we fielded many questions, despite the fact that we testified at the end of a four-hour hearing.

In fact, MPhA's points were so well

received that the Task Force asked us to present a pharmacy benefit program that could be incorporated into the final standard benefits package.

Starting immediately after that meeting, a work-group of members from both the MPhA Legislative Committee and Third Party Committee met to draft a workable pharmacy benefit. Once this first draft was created, it was shared with the Legislative Committee of the Maryland Association of Chain Drug Stores. MACDS made several recommendations to improve the draft and these were incorporated. Our next step in the development process is to share this document with both the University of Maryland School of Pharmacy and the Pharmaceutical Manufacturers Association. MPhA and MACDS have shared their first joint draft with the Standard Benefits Task Force and will provide the refined version as a final document once all other groups have had input.

The following is a summary of the pharmacy benefit proposed by MPhA and MACDS. It is important to realize that this is only a proposal; it is not the final document. The Standard Benefits Task Force will report back to the entire HCACC who must then make a decision as to whether the package (including pharmacy) meets with the objectives of Maryland's health care reform legislation.



### Objective

To provide an outpatient (ambulatory) pharmacy services benefit as part of the standard health care benefit that balances the needs of beneficiaries with the costs to small employers.

### Assumptions

The pharmacy services benefit will be a mandatory part of a standard health benefit package. The benefit is "risk" based and mutually shared between the patient, insurer and employer. The benefit does not provide first dollar coverage but is instead designed to protect those with the greatest need for protection. Four types of coverage will be available: individual, parent/child, husband/wife, and family.

### Coverage

Benefits are covered only when a prescription order is prescribed by an authorized prescriber for a covered member of an eligible dependent.

Covered benefits include FDA approved federal legend drugs which require a prescription subject to the general and specific exclusions listed below. Insulin, insulin syringes, and diabetic testing supplies should also be included.

### General Exclusions

- Any Federal Legend drug in which the intended use has not been approved by the FDA and is

therefore termed investigational.

- Immunization agents, biological sera, blood or blood plasma.
- Medication for which the cost is recoverable under any Worker's Compensation or Occupational Disease Law or any state or governmental agency, or medication furnished by any other drug or medical service for which no charge is made to the recipient.
- Drugs lawfully dispensed without a prescription, except insulin (OTCs).
- Any experimental drug.
- Any charge for the administration of any drug.
- Medication which is to be administered to the individual by a prescriber or in the prescriber's office.
- Prescriptions dispensed by an authorized prescriber.

### Specific Exclusions

- Drugs for cosmetic purposes (Rogaine, Retin-A for patient age greater than 25)
- Fertility drugs, unless fertility services will be a part of the standard benefits package.
- Home administered nutritional products (intravenous and oral)
- Anorectics
- Smoking cessation products, unless smoking cessation programs and services will be part of the standard benefits package.
- Therapeutic or prosthetic devices with or without a prescription.
- Injectable products *not* designed for patient self-administration.

### Drug Coverage

The pharmacist must dispense generic products where available except where prohibited by Maryland law. The patient may elect to pay the difference between the generic price and the brand name price if the brand is desired. Coverage and payment of a branded product when an approved generic substitute is available may occur if the authorized prescriber specifies that the brand is "medically necessary."

The lesser of a 30 days supply or 100 unit doses may be dispensed by the pharmacist.

Up to a 100 days supply may be dispensed by the pharmacist if the product is listed on the approved Maintenance Drug List; patient will pay one copay. Up to six months of oral contraceptives may be dispensed at one time, pending prescriber authorization; patient will pay one copay per cycle.

Refills may be dispensed for up to one year from the date of original dispensing, subject to the limits of the prescription and/or federal law.

No refills will be permitted until 75% of the previous fill has been consumed. An override system will be provided for the pharmacist to make arrangements in special circumstances (changes in dose, vacations, lost prescriptions, etc.).

For cost-containment efforts, a therapeutic formulary which would encourage prescribers and dispensers to use preferred products may be instituted.




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### **Quality Control**

On-line, interactive prospective drug utilization review must be a component of the pharmacy services benefit. Participation and cooperation in the Pro-DUR program is required by benefit providers. Retrospective drug utilization review is also an intertwined component. All Pro- and Retro- DUR programs must comply with criteria developed by the Maryland Drug Utilization Review Board.

### **Provider Requirements**

Participating pharmacies must maintain computerized patient profiles, have access to drug/drug interaction software and participate in on-line eligibility verification, claims transmission, and drug utilization review.

### **Patient Requirements**

Patients will be responsible for meeting annual prescription benefit deductibles. These deductibles are:

- Individual - \$200/year
- Parent/Child - \$350/year
- Husband/Wife - \$350/year
- Family - \$400/year

Once annual deductibles have been met, copayments are 20% of the allowable price or \$5.00, whichever is greater.

### **Program Requirements**

The selected benefit administrator for the carrier (insurer, PPO, or HMO) must have the capability of electronic fund transfer within seven days of receipt and approval of claim. The carrier or its administrator must conduct an open-bid process if establishing a limited pharmacy provider network.

The benefit provide compensation for pharmaceutical care services over and above the dispensing of a prescription. These services would include, but not be limited to: incentives for formulary compliance or conversions along guidelines established by the plan, counseling services about compliance and medication behavior, non-dispensing of a prescription if the prescription is unnecessary or would adversely affect the patient's health.

### **Reimbursement**

Reimbursement should be structured to mirror the current Maryland Medical Assistance (Medicaid) formulas. In Medicaid, the cost of the drug is based on Wholesale Acquisition Cost (WAC) plus 10% plus a sliding scale dispensing fee. Another alternative would be to reimburse at the 90th percentile of the usual and customary charge for each prescription. **R**



# Switched Labels

David B. Brushwood, R.Ph., J.D.



The Supreme court of New York, Appellate Division, recently reported a case in which the underlying allegations are that a pharmacy negligently switched the labels of two medications. The case was initially dismissed at the trial court level because the plaintiff was held to have failed to meet several procedural requirements, and because the plaintiff was held to have failed to show that the injury suffered actually resulted from the negligence of the pharmacy. The appellate court held both that the procedural requirements had in fact been met, and that the plaintiff had established a case of negligence on the part of the pharmacist in switching the labels.

The two medications in question were an antibiotic and an analgesic. The patient was using them to treat pneumonia and bronchitis. According to the court, as a result of the dispensing pharmacist's negligence, there was a three-week delay in the patient's antibiotic treatment, which caused the patient to suffer progressively worsening symptoms of coughing, fever, sweating and hallucinations. Apparently the patient was not suffering pain, or for some other reason decided not to use the medication that was labeled for pain (of course, this was in reality the antibiotic). The eventual outcome for the patient is not reported in the opinion.

This case raises the issue of avoidable versus unavoidable error. Because pharmacists are human, and because humans make mistakes, it is axiomatic that pharmacists will make mistakes. However, it might be possible to institute procedures that decrease the likelihood of an error. For example, it might be possible to process one prescription completely before even starting to process the next prescription. If this were done, then it would be unlikely that the label for the first prescription would be affixed to the vial of the second prescription, and vice versa (as happened in this case), because the first label would already be affixed to the first vial before the second label came into existence. Patient counseling, with visualization of the tablets or capsules as part of a counseling session, would also reduce the possibility that a dispensing error would go undetected before a patient left a pharmacy with a medication. Procedures such as these might make it possible to avoid seemingly unavoidable errors. R

Based on *Drennon v. Faris Pharmacy*, 1993 N.Y. App. Div. Lexis 9242 (October 1, 1993).

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## Dickinson's Pharmacy

*Jim Dickinson, Editor, Dickinson's Pharmacy*

"When you lie down with a dog, you're liable to get fleas." That was American Pharmaceutical Association executive vice president John A. Gans' good-humored acknowledgment, in private, a few days after he persuaded his board to make a shocking deal with Medco Containment Services' wholly-owned PAID Prescriptions subsidiary.

He invited teams of Medco, PAID, and Merck executives to make promotional presentations to his board and to assembled state pharmaceutical association executives at APhA headquarters during the weekend of September 18-19, after which the board voted in favor of formally endorsing PAID's "Coordinated Care Network."

That Gans could within a few days refer rhetorically to his new partner as if it were a dog didn't mean he was having second thoughts already. Still fervently convinced of the merits of PAID's promises to pay pharmacists for cognitive services, Gans was simply acknowledging reality - community pharmacy despises Medco and abhors the pending Merck merger.

And there is no doubt that Medco has spent the last decade in pharmacy acting like an animal - be it a hyena or a flea-bitten mongrel dog, or the more generous image offered by former PAID executive Marcel Laventurier (who tried to sell the company to APhA in 1965); a "tiger."

Directed by the brilliant and voracious Martin J. Wygod, Medco has thumbed its nose at state laws governing the practice of pharmacy,

twisted the arms of pharmaceutical manufacturers until they abandoned their traditional customers by extending retail-deadly discounts to Medco, trampled on the professional ideals of its employee pharmacists, and brazenly lied to investigators, its clients and most of all the media about its behavior.

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*There is no doubt that  
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mongrel dog*

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Only a month before APhA endorsed PAID's new network - which was spawned out of negative financial market reactions to the merger with Merck - a terrified former employee of Medco's National Rx mail-order operation came to me with new disclosures about the company's alleged lawlessness. This pharmacist was just the latest among other Medco pharmacists who have done the same thing out of stricken consciences.

Technicians, Pharmacist X told me (I agreed to shield the pharmacist's identity), were illegally calling prescribers and interpreting prescriptions so successfully at one of Medco's Florida facilities that management decided to expand their role. The plant's ratio of pharmacists to technicians had been raised to an effective 1:6, far in excess of the state's 1:1 limit (or 1:2

by special waiver if the second technician is restricted to data-entry).

I was given an obviously-authentic November 11, 1992 Medco interoffice memorandum by supervisor Chris Asaro advising that the company's ratio henceforth will be 1:3, which pharmacist X says works out in practice to mean peaks as high as 1:6 when client tours or board inspections are not taking place. When they are, job stations are rapidly switched during the five minutes' notice that the facility gets before each tour or inspection; technicians leave the pharmacy area and hide in other rooms. Medco pharmacists in Ohio and Texas have told me the same thing over many years.

Obviously unaware of the clandestine overtures that even then were being made to APhA by Medco, Pharmacist X predicted that in the brave new world for pharmacy being created by Medco there would be only one valuable function for pharmacists - calling prescribers in Medco's grotesquely lucrative "Prescriber's Choice" program that persuades doctors to change drug choices in favor of products on which Medco has secured an exclusive price break or kickback. Breaks like \$2.58 for Aerobid Inhaler System 7 gm that costs independents around \$33 (according to price-discrimination lawsuits filed in August against Medco, Bergen Brunswig, McKesson and four manufacturers by Fred Mayer's Pharmacy Defense Fund).

And Pharmacist X told of outright kickbacks, such as the \$250 that one company was paying for each Rx that

Medco pharmacists switch from a competing product to its brand in the Prescriber's Choice program in exchange for a guaranteed share of market; according to Pharmacist X, such kickbacks effectively reduce Medco's acquisition cost nearly to zero and may explain in part the sharp rise in the drug's price to non-Medco accounts.

As Ohio state pharmacy executive Ernest Boyd commented after hearing the APhA-Medco presentations: "It simply plugs community pharmacies into Prescriber's Choice."

Pharmacist X said pharmacy board inspections were regarded as a joke by Medco pharmacists because the facility is so organized that inspectors simply don't know what they're looking at. As for monitoring the lawfulness of Prescriber's Choice telephone detailing and Medco's other professional conversations with prescribers, "it would take 160 agents to monitor all the calls that go out of that place - and what would a \$100,000 fine matter to Medco, anyway? It would be just a cost of doing business."

All of which paints a picture of a practice setting that is beyond public scrutiny or control. Although Pharmacist X brought his evidence before the Florida Pharmacy Board in March, no publicly visible action had been taken by September. Board executive director John R. Taylor told me it was illegal for him to confirm or deny the existence of any investigation.

Despite such frightening pictures of citizen Medco, APhA's Gans

fearlessly met with Medco senior vice president of strategic marketing and development Per G.H. Lofberg on numerous occasions before the Merck merger announcement, and introduced him to APhA president Lowell J. Anderson.

Both pharmacist say they recognized in Lofberg's demeanor and hours of philosophizing a kindred spirit in the highest aspirations they share for pharmacy, health care and citizenship. The intense, well-documented conversations showed PAID as being far ahead of anyone else in its capacity to swiftly change pharmacy for the better.

But Anderson and Gans say they also recognized that what might be driving Medco in its overtures could be stock market criticism of the Merck-Medco merger's greatest weakness - namely, Medco's appalling image in the pharmacy world; what better way to repair it than to secure an APhA endorsement?

That possibly "ulterior" motive didn't worry either Gans or Anderson. They might sup with the Devil if that would profit the profession. Their supping gave them a glimpse of PAID reversing the declining fortunes of thousands of smaller pharmacies -- at least \$2,000 more revenue per annum, worst case, if the smallest pharmacy entered into the network's spirit, Gans calculates. I bluntly asked Anderson: "Then you believe the leopard can change its spots?" Earnestly, he responded: "Yes, I do."

Laventurier, who wasn't privy to

any of the discussions, but who has had a lot of dealings with Medco and its key players over the years, answered the same question much more forcefully: "No, the leopard cannot change its spots."

In their own ways, most of the state pharmaceutical association executives who heard the presentations at APhA headquarters shared Laventurier's skepticism, mingled with a strong sense of wishful thinking. If it could have been anybody else but Medco, then any plan that routinely pays pharmacists for their cognitive services, and lifts them out of life-and-death dependence on ever-slimpier product margins, must be encouraged.

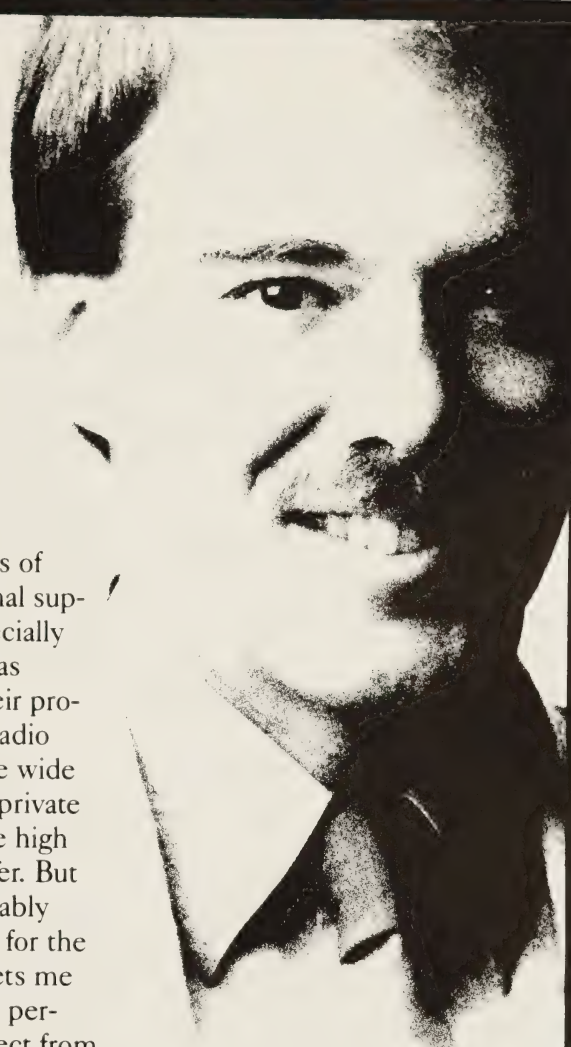
Of course, this network should have been set up by PCS, which instead became a lip-servant to high-minded studies and demonstration projects that did nothing to halt the avalanche of small pharmacy closing around the country.

The grim reality is that it was Medco - dog, hyena, tiger or the Devil himself - that came forward in the shining garb of guardian angel to rescue community pharmacy from the edge of extinction. And APhA grabbed the opportunity, even if with significant misgivings.

Is it churlish and mean to point out in this moment of joyous relief that the aforesaid edge of extinction was thrust into community pharmacy by Medco and its imitators in the animal pack that is managed care?

*Concluded on page 25....*





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# Drug Information Questions

Dawn Stull, R.Ph., Pharm.D. II, Babette Prince, Pharm.D.  
UMAB Drug Information Center

*This article provided under a grant-in-aid from Glaxo*

Can cefaclor cause serum sickness reactions? Is the incidence higher in children?

Cefaclor is an oral semisynthetic cephalosporin that was first marketed in 1979 to treat a wide range of both gram-positive and gram-negative infections. Cefaclor is prescribed to treat otitis media, skin and skin structure infections, bronchitis, and upper respiratory tract infections.<sup>1</sup> The most commonly reported adverse effects with cefaclor include gastrointestinal complaints and serum sickness-like reactions. The latter has been found to occur predominantly in children and is usually observed during the second administration of the antibiotic.<sup>1,2</sup> There are more reports of serum sickness-like reactions after cefaclor therapy than after treatment with other antibiotics.<sup>3</sup>

Serum sickness is a systemic immunologic disorder that is classified as a type III hypersensitivity reaction. This reaction follows the ingestion of foreign proteins and chemicals which leads to the formation of antigen-antibody complexes and subsequently to skin, joint, and systemic manifestations.<sup>4</sup> These reactions are characterized by the presence of a circulating immune complex, lymphadenopathy, proteinuria, urticaria, and joint involvement. The serum sickness-like reaction caused by cefaclor presents with the same skin and joint involvement but lacks the systemic manifestations mentioned above.<sup>2</sup>

The reported incidence of serum sickness-like reactions seems to vary between studies, however, all seem to agree that children have an increased risk of developing the adverse effect. One study conducted by Eli Lilly and Company involving a large sample size (8,346 patients) and a long time frame (10 years) found the incidence of this hypersensitivity reaction to be 0.024% (2 cases) This varies significantly from other studies which reveal an incidence as high as 3.4%<sup>2</sup> This large difference may be attributed to the fact that the Lilly study involved a sample with a larger age distribution and an extended time course of study. As of 1988, Lilly had received 1400

case reports of reactions similar to serum sickness with two thirds of these occurring during the second administration of the drug.<sup>2</sup>

There are several factors that may predispose a patient to developing serum sickness-like reactions. These include age, prior antibiotic exposure, and possibly the season of the year. The reaction commonly occurs in children younger than five years of age during the second or third course of therapy with cefaclor.<sup>2</sup> Some studies have suggested that there is an increase in serum sickness-like reactions during the winter months when compared to the other seasons. This implies that the presence of a cofactor, such as an infectious agent, may increase the incidence of this reaction during or after cefaclor therapy.

The clinical presentation is characterized by urticarial eruptions, pruritus, and arthritis or arthralgias. The average time between the initiation of therapy and the development of the adverse reaction is seven days with a range of two to ten days. The dermatologic manifestations seem to be the most common with an incidence of 64%, while the arthralgias or arthritis occurs in 17% of patients.<sup>3</sup> Most children have erythema that progresses to urticaria. Many of these urticarial wheals initially have dusky to purple centers suggesting erythema multiforme. However, serum sickness-like reactions can be differentiated from erythema multiforme based on the fact that the lesions are migratory and there is no mucous membrane involvement. Joint involvement includes edema, decreased range of motion, warmth, and pain, with the hands and feet most commonly affected. In terms of laboratory studies, most patients have an elevated WBC, normal platelets, and possibly slight proteinuria, however, these tests are not diagnostic for serum sickness-like reactions and are not needed to confirm a diagnosis.<sup>2</sup>

The treatment for serum sickness-like reactions involves the discontinuation of cefaclor therapy and the use of systemic steroids and/or antihistamines. The exact recommendations for the use of these agents has yet to be determined. One case involving a 6 month old female who developed a serum sickness-like reaction was treated with oral diphenhydramine. The patient's symptoms

resolved spontaneously within 48 hours. In another case, a 14 month old male was treated successfully with a course of oral prednisone 1 mg/kg/day and cefaclor therapy was discontinued. While these treatments offer symptomatic relief, the impact of these medications on the time course of the illness has not been determined.<sup>2</sup>

There is no effective mechanism to prevent this serum sickness-like reaction from occurring other than to avoid rechallenge with the antibiotic since the reaction usually occurs during the second or third course of therapy. In the cases reported, the reaction seems to be self limiting and resolves when cefaclor is discontinued. In order to effectively manage this reaction, the clinician should be aware of the factors that predispose a patient to its development, and recognize the presentation of symptoms while they are still in the early stages.

In summary, cefaclor, commonly used in the treatment of otitis media and upper respiratory tract infections, has been found to be responsible for the development of most serum sickness-like reactions reported in children. These reactions are commonly seen in patients less than five years old and are more likely to occur during the second or third course of therapy. This reaction is characterized by the presence of urticarial eruptions and arthralgias. Treatment appears to be symptomatic in nature and includes the use of antihistamines and steroids. It is important for the clinician to be able to differentiate serum sickness-like reactions from more serious skin reactions such as erythema multiforme in order to initiate proper treatment and follow up. **R**

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## Dickinson's Pharmacy

*Continued from page 22*

Were NARD and NACDS spoilsports when they threw cold water on the deal for its potential to damage "the advances we have made on behalf of community pharmacy" in the Clinton Administration against discriminatory pricing, mail-order and closed pharmacy panels.

Was it a low blow for them to say in a press release that "in our commitment to secure our future we cannot jump at every offering that uses the "hot button" words and phrases we want to hear. NARD and NACDS firmly do not believe that community pharmacy's future is best served by relinquishing the distribution of pharmaceutical to mail-order companies."

For no matter what APHA, Medco or Merck may want us to think, PAID remains - perhaps irretrievably - tainted by its in-house Medco mail-order connection. As Connecticut state pharmacy executive Dan Leone put it: "You can't just wave a magic wand and turn a bad guy into a good guy."

Yet Lowell Anderson reminded us of the Rabin-Arafat handshake on the White House lawn, and the ever-accelerating pace of change in today's world. Things that are unthinkable at 10 o'clock can be acceptable by 4 o'clock. Of a dozen fellow retail pharmacists in Minneapolis whom he polled at random on the PAID deal, all supported it.

PAID-Medco ambassadors to APHA painted a picture of a new pharmacy world in which Medco might even sell off its mail-order operations, so committed is it now becoming to the better future it sees for community pharmacy. On the other hand, they didn't promise to stop selling contracts with mail-order prescription incentives in them -although Gans says he has such an assurance from Medco.

You make up your own mind. As for me, I'm too old to jump this fast.



## Continuing Education Quiz

November 1993 -- American Health Security Act

This month's questions are taken from the article on President Clinton's health reform proposal in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by April 30, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

1. The premiums for health plans will be paid by:
  - a. 80% employer/20% employee
  - b. 80% employee/20% employer
  - c. 80% employer/10% employee/10% state
  - d. 80% employee/10% employer/10% state
2. The national health benefit includes both prescriptions and durable medical equipment.
  - a. true
  - b. false
  - c. undecided at this time
3. The regional health alliances (RHA) must provide:
  - a. a fee-for-service plan
  - b. an HMO plan
  - c. a preferred provider or POS plan
  - d. a and b only
  - e. a, b, and c
4. The Clinton proposal specifically includes patients' right to the provider of their choice.
  - a. true
  - b. false
  - c. undecided at this time
5. The Department of Justice/FTC is charged with:
  - a. repealing health insurers antitrust exemption
  - b. allowing providers to negotiate collectively
  - c. providing HMOs with an antitrust exemption
  - d. a and b only
  - e. a, b, and c
6. Medicare recipients must retain their Medicare coverage (plus prescription drug benefits). They may not join a health plan approved by the RHAs.
  - a. true
  - b. false
  - c. undecided at this time
7. Patients will pay pharmacy copays of:
  - a. \$5 for plans/\$5 for Medicare
  - b. 20% for plans/\$5 for Medicare
  - c. \$ 5 for plans/20% for Medicare
  - d. 20% for plans/20% for Medicare
8. The elimination of discriminatory pricing is based on manufacturers who want their products covered by Medicare and Medicaid.
  - a. true
  - b. false
  - c. undecided at this time
9. The \$5 dispensing fee, indexed to the Consumer Price Index, applies to:
  - a. all health plans and Medicare
  - b. all health plans only
  - c. Medicare only
  - d. all health plans with a phase-in for Medicare by 1997
10. The National Health Board will be responsible for assuring that new pharmaceutical are priced reasonably.
  - a. true
  - b. false
  - c. undecided at this time

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# Statement of the NWDA

*On National Health Care Policy and Pharmacy*

*Ronald J. Streck, President, NWDA*



With health care reform a national concern, the government is facing the difficult challenge of expanding access to high quality health care services at an affordable price. As a vital link in the delivery of pharmaceutical care to America's consumers, the wholesale drug distribution industry stands ready to help the country meet those goals.

The National Wholesale Druggists' Association (NWDA) is the national trade association for full-line, full-service drug wholesalers. Its members operate 250 distribution centers across the country that handle more than 98 percent of the wholesale sales of pharmaceutical products nationwide. With an effective income tax rate of 32 percent, the industry contributed more than \$230 million in taxes in 1991, not including the taxes paid on wages for the more than 14,000 Americans the industry employs.

Today, the wholesale drug distribution channel is unquestionably the most cost-effective means for pharmaceutical manufacturers to deliver product to market. Drug wholesalers distribute approximately 75 percent of prescription drugs in the United States, up from 57 percent in 1980. This increasing market share reflects the efficiencies and value-added services that wholesale drug distributors offer both their suppliers and pharmacy customers.

The wholesale drug distribution industry has a strong record of innovation and efficiencies. As a result, it has saved billions of dollars in the health care marketplace through lower operating costs. Drug

wholesalers dramatically lowered their operating expenses from 9.2 percent of net sales in 1979 to 4.4 percent in 1991. This in turn allowed drug wholesalers to lower their gross margins from 11.3 percent of net sales in 1979 to a slim 6.8 percent in 1991. As a result, the industry's sales grew from \$5.5 billion in 1979 to \$36.2 billion in 1991. On this amount, the industry earned a net profit of just over 1 percent.

Operating in a highly competitive marketplace, wholesale distributors have passed the savings from lower operating costs on to their customers. These customers constitute the entire range of health care facilities: independent retail pharmacies; chain drug stores and warehouses; hospital pharmacies; supermarkets and pharmacies; clinics; HMO and managed health care pharmacies; nursing homes; physicians; mail order; mass merchandisers' pharmacies; prisons; and state and federal institutions.

The latter category - government institutions - is rapidly increasing as a customer of wholesale drug services. Sectors of the federal government, with the Department of Veterans Affairs (DVA) and the Department of Defense (DOD) being dramatic examples, have recognized that their manufacturer-direct purchasing systems are inefficient. In 1990, the DOD evaluated its inventory system and recommended increased use of commercial distribution systems, stating that "increasingly constrained resources and facilities are unnecessarily tied up through investment in material and



warehousing of items (that are) available through commercial distribution systems." A December 1991 report from the General Accounting Office further recommended that the DOD use commercial practices to achieve greater efficiencies. Another government-study, published in September 1992 by the Logistics Management Institute (LMI), reached similar conclusions in regard to the DVA. It noted that the DVA "is testing a new distribution system - based on commercial distribution models - that is reducing inventories and improving response time." LMI added, however, that the DVA must change more aggressively "to significantly improve responsiveness and reduce distribution costs." Since those reports, the DOD and DVA have turned to commercial wholesale drug distributors to save millions in expenses while improving service.

NWDA wholesaler members also provide their customers with a multitude of value-added services, ranging from inventory management support and computerized business management reports to pharmacy computer systems and coded shelf labels. In addition, through investment in state-of-the-art distribution and information technologies, the industry has increased its ability not only to save money, but to offer nearly error-free order fulfillment on a standard turnaround of 24 hours or less.

Besides providing timely, accurate and cost efficient distribution of health care products, the wholesale drug industry also provides *safe*

## NWDA Position Statement

### *Preferential Pricing Policies*

NWDA believes the primary responsibility of the health care delivery system in this country is to serve the needs of the consumer and that all health care decisions and policies must be developed with the public interest in mind. The public interest is best served when the free enterprise system is allowed to function. NWDA opposes preferential pricing policies that are not based on meaningful functional categories or volume purchasing of all products.

distribution. Wholesale drug distributors are government-licensed operations and adhere to stringent storage and handling procedures designed to ensure the integrity of the medications they distribute and to keep product from being diverted into illicit channels. Wholesale drug distributors adhere to strict procedures with respect to such issues as recordkeeping, security, temperature and humidity requirements, personnel training, return and recall handling, emergency planning, and receipt and distribution of products.

### **The Need for a Pharmaceutical Benefit**

Because its members are committed to providing efficient and safe delivery of pharmaceuticals to the health care marketplace, NWDA is

equally committed to the belief that the cost-effective chain of pharmaceutical benefits be extended beyond the delivery truck. NWDA believes that any minimum health care benefits package should include coverage of pharmaceutical therapy and care to ensure that consumers have guaranteed access to one of the most cost-effective and beneficial portions of the medical care system.

Appropriate pharmaceutical therapy and care not only improve the quality of life for millions of Americans, but also help lower overall health care expenditures by reducing the need for more costly medical interventions - such as surgeries, hospitalizations, long-term institutional care and repeated visits to a physician - and by improving premature morbidity and mortality rates, especially among infants. To give just a few examples, a study by

## NWDA Position Statement

### *Different Classes of Trade*

NWDA believes that manufacturers' policies and procedures must ensure that all classes of trade and individual customers are treated fairly and equitably regarding prices, terms, promotions, deals and package sizes within a particular level of distribution. NWDA encourages a marketing approach which is least disruptive to normal business functions and is equal among members of each distribution level.

Changes in the pharmaceutical and health care products industry, as well as changes in consumers' buying habits, have led to the evolution of a wider variety than ever before of specialized wholesaler formats utilized in the distribution of pharmaceutical and health care products. The historic distinctions among traditional classes of wholesalers have become blurred. Health care product manufacturers should be aware that, while there may be some wholesalers utilizing various specialized distribution formats which may have their own unique characteristics, these different classes of wholesalers are indeed competitors in the distribution and sale of pharmaceutical, health care and other products to health care providers. Health care product manufacturers should therefore recognize the importance of dealing fairly, consistently and lawfully with all wholesalers.

The Robinson-Patman Act also provides that in the pricing and promotion of products, manufacturers should not differentiate among competing wholesale customers within the same market area based on artificial "class of trade" or other types of distinctions. A manufacturer, in fashioning pricing and discount programs, must carefully consider how a customer performs in the marketplace and not what functional label the customer uses to identify itself. If a manufacturer develops prices, terms, promotions, deals or package sizes designed to meet the marketing needs or desires of a particular class of trade or specialized wholesaler format, the manufacturer should inform all competing wholesale customers within the same market area, regardless of class of trade or label, of their availability and should grant these wholesalers an equal opportunity to qualify for these offerings.

Wholesalers also should not request special prices, allowances or services from manufacturers or their agents if they know that to grant such prices, allowances or services would force the manufacturer to discriminate unlawfully against other customers within the same market area. This will promote fairness within the industry and benefit the consumer.

California's Medi-Cal system found that the use of prescription medication to avert coronary events by reducing blood fats produced annual savings for more than \$5 million. In another example, a DVA study found that for many patients medication was as effective as coronary artery bypass surgery while costing \$300 a year compared to

\$41,000 for surgery. Finally, former Health and Human Services Secretary Louis Sullivan stated last year that new drugs to treat respiratory distress have cut infant deaths 8 percent a year since 1989. These are just a few of the many examples that could be cited to show the positive impact pharmaceuticals have.

## Pharmaceutical Therapy

Under the current system, appropriate pharmaceutical therapy is far from guaranteed for health care consumers. In many cases, pharmaceuticals represent the largest out-of-pocket expense for consumers. The ability to pay is directly related to patient compliance and therapy outcome. Simply put, if patients do not have access to pharmaceuticals because they cannot afford the out-of-pocket expense, therapy can be incomplete, mismanaged or never initiated. When treatment fails at this point, it quite obviously is a waste of resources, and more importantly, could seriously impair the patient's health and quality of life. It also is more likely to lead to a greater total treatment cost if more serious and expensive intervention is then necessitated.

NWDA advocates that any minimum health care benefits package should include all components of a proper course of therapy. This includes coverage not only of out-of-hospital prescription drugs, but, when deemed necessary by a licensed health-care practitioner, over-the-counter (OTC) medicines and medical appliances as well. All of these products, when utilized under the proper supervision and direction of a licensed health-care practitioner, are essential to an individual's health and well-being.

## Pharmaceutical Care

Coverage of pharmaceutical products is only the first step in ensuring that both the patient and the health care system receive the greatest benefit from pharmaceutical therapy. A complete pharmaceutical package also should include coverage for pharmaceutical care and services. The pharmacist, working in conjunction with the rest of the health care team, can have a great impact in managing a patient's course of drug therapy to ensure that a patient complies with treatment

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## NWDA Statement

*Concluded from page 30.*

instructions. The pharmacist also can review that the proper medication is prescribed in the proper dosage for given patient and the treatment is compatible with other medications a patient may be taking. By working to achieve optimum outcomes, these measures address both the quality of health care treatment and cost efficiency.

Any pharmaceutical benefit should recognize that patients may need different levels of pharmaceutical care. To maximize therapeutic outcomes - thus providing the most effective and economically sound treatment - a pharmacist must manage the drug-use process by addressing a patient's individual needs. Thus, any pharmaceutical benefit should encourage and support access to a wide range of services - including drug utilization review and patient outcome analysis - and provide the pharmacist the flexibility to tailor the services to the individual patient.

## Summary

The goal of health care reform should be to promote efficient, cost-

effective and beneficial treatment. With that objective in mind, a full-fledged out-of-hospital pharmaceutical benefit is a required element of a minimum benefits package in a successful health care reform plan.

An efficient and cost-effective system for delivering pharmaceutical products and care - from the discovery of the drug in the research center through the warehouse until the patient is declared well - is in place today. At just 7 percent of the nation's health care expenditures, pharmaceuticals and related health care products - when utilized in the proper manner and under the appropriate supervision - are among the most cost-effective methods of health care available. Under the current health care system, however, pharmaceutical care is underutilized to the detriment of both the patient and the system.

Wholesale drug distributors offer dramatic proof that it is possible to reduce costs while increasing quality service. Wholesale drug distributors have made and will continue to make a significant contribution to reducing the bottom line on health care expenditures. We welcome the opportunity to work with this subcommittee, Congress and the administration as we all strive to ensure that the American public receives both the best and the most cost-effective health care. **R**





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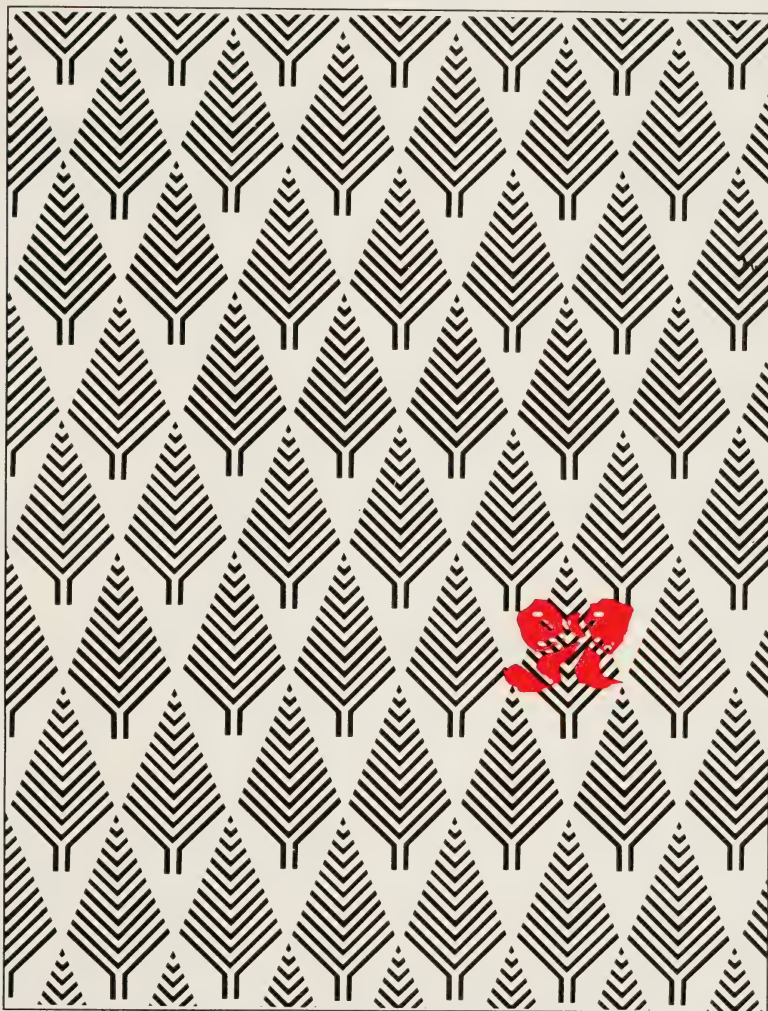
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# *The Maryland Pharmacist*

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NO. 12



*"Tie One On"  
For the Holidays*



## Looking to the Future

The 1994 Mid-Year  
Educational Meeting

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February 6, 1994

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Maryland Pharmacists  
Association

## Tentative Program

8:00 - 8:45 am      Registration and Continental Breakfast  
*Atrium*

8:45 - 9:00 am      **President's Welcome**  
Howard R. Schiff, P.D.  
MPhA President  
*Chesapeake Ballroom*

9:00 - 10:00 am      Continuing Education Seminar  
**The Future of Pharmacy in the  
American Health Care System**  
*Chesapeake Ballroom*

10:00 am - 12:00      Continuing Education Seminar  
**Implementing Pharmaceutical Care  
Practical Applications**  
*Chesapeake Ballroom*

12:00 - 1:00 pm      Buffet Luncheon  
*Atrium and Windjammer*

1:00 - 4:00 pm      Continuing Education Seminar  
**New Drugs and Drug Therapies  
for 1994**  
*Chesapeake Ballroom*

4:00 - 5:00 pm      **Business Session**  
MPhA House of Delegates  
Speaker Alisa Billington presiding

1.    Role Call of Delegates
2.    Legislative Briefing
3.    Nominations for MPhA Elections
4.    Nominations for Maryland Board  
     of Pharmacy
5.    Briefing: UMAB School of  
     Pharmacy Non-Traditional  
     Pharm.D. Program
6.    Other Business

**Complete program information will be  
mailed to all pharmacists this month!**



# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

December 1993

Volume 69

Number 12

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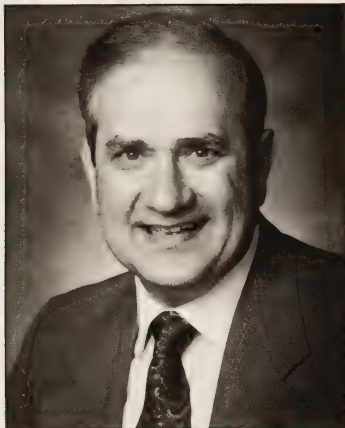
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## President's Commentary

*Howard Schiff, P.D.*



In the space of 15 months in 1986 and 1987, my wife and I lost both a close friend and a niece to drunk driving crashes. These tragic incidents have lifelong effects on the families and friends of the people involved. The survivors often need professional help to cope in the ensuing years. I can still recall what I was doing when I heard the news of each, just as those of us old enough can remember what we were doing when we heard of President Kennedy's assassination. I'm sure each of us has memories of a friend or acquaintance lost to drunk driving crashes. I say "crashes" and not "accidents" because as Donna Becker of Mothers Against Drunk Drivers says in her "Holiday Message" on page five, "someone has intentionally made a choice to drink and drive" and, therefore, accidents is too kind of a word. Driving a vehicle is comparable to handling a weapon and doing so when impaired by drugs or alcohol increases the risk exponentially.

What can we as pharmacists do? Why did MADD choose to work with the Maryland Pharmacists Association? They came to us because we are the medical professionals with the most knowledge of the effects of drugs and alcohol. We are trusted, respected and perceived as accessible, inexpensive with our advice, and willing to serve. We are seen as community helpers, regardless of where we work or practice.

In this era of health care reform, of reduced reimbursements, of the contraction of the number of pharmacies able to remain viable, here is one more reason -- one not often cited -- why the profession must survive; it is our service to our communities.

**R**

# A Holiday Message

*Donna Becker, Mothers Against Drunk Driving, Northern MD Chapter*



As we enter the holiday season, I have very mixed emotions. On one hand, this is supposed to be a happy, joyous time as we get together with family and friends to celebrate and renew friendships. But with these celebrations can sometimes come tragedy because of holiday parties where alcohol is served and consumed in large amounts. Because of these parties, the holiday season is traditionally a time when the number of deaths on the highways increases, especially from alcohol-related crashes. These numbers can be lowered, however, by making people more aware of the consequences of drinking and driving and by giving people alternatives when they attend parties or any seasonal functions.

First, I would like to tell you some of the consequences that have occurred by combining alcohol and driving. The statistics are staggering; last year alone there were 19,900 deaths on our highways from alcohol-related crashes. Along with the deaths, there were 345,000 injuries, 45% of which were serious. These are large numbers to comprehend, but if we break them down, it averages out to one person is killed every 23 minutes by a drunk driver. Think about that. If it takes you 23 minutes to read this journal, one person will have already died!

Here is another interesting fact: alcohol-related crashes are the leading cause of death for Americans between 16 and 24 years of age. That is a very frightening thought when you realize that because of drunk drivers, many of our youth who might have grown up to become great leaders, scientists, teachers, etc. are losing their lives so early because

someone make the choice to drink and drive.

And it is a conscious choice - that is why we in MADD call these crashes instead of accidents. An accident implies that no one is at fault. But in a drunk driving crash, someone has intentionally made a choice to drink and drive. They did not intentionally set out to kill or injure someone, but they did decide to drive after drinking.

***If you break down the annual statistics, one person is killed every 23 minutes by a drunk driver***

A very effective campaign that MADD started to educate the public about the dangers of drinking and driving is the "Tie One On Campaign" - tying a red ribbon on to your car or other vehicle. This ribbon serves as a reminder to all who see it not to drink and drive. Across the state of Maryland over two million ribbons are distributed each year. What a powerful, but simple, way to educate about drinking and driving. There are no lectures, no sermons, just a simple, visual message.

MADD has hundreds of volunteers each year who cut, staple and count out red ribbons to be distributed. These volunteers are from senior centers, Girl Scout troops, schools and community groups, as well as individuals who work from their homes. We also have other volunteers who distribute the ribbons to various locations around the State. The ribbons are made available through schools, libraries, post offices,






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MVA offices, local businesses and many more places. Now, the Maryland Pharmacists Association is joining with us in helping alert their patients about the dangers of drinking and driving. Without our volunteers, this campaign would not be so successful and we are grateful for all of their help.

I said at the beginning of this article that I have very mixed emotions about the holidays. Now I would like to tell you why. Christmas 1984 was a joyful and fun-filled time for me. My husband and I spent the day at my sister's house with other members of our family. It was a day filled with presents, laughter, good food, and much happiness. Little did I know at the time that it would be the last Christmas I would spend with my sister, because one month later, at the age of 26, she was dead, killed by a drunk-driver. He had made the choice to drink and drive, without thinking of the consequences. And in one violent crash, he wiped out my sister's life and destroyed a very vital part of my family.

None of us has been the same since. And almost nine years later, the pain is still very great. I have learned to deal with it, but the pain will never go away and I cannot enjoy the holidays in the same way again. Each time my family gets together, no matter how many people are around, there is still someone missing and I feel the loss all over again. I think back to the Christmas seasons we enjoyed with her, and how much she loved giving gifts and then I start to hurt all over again because I know that she will never again be with us.

This loss and pain that I have suffered is something that I would not wish on anyone. That is why I try so hard to educate people about the consequences of drinking and driving. It is easy to say that if you drink and drive you are only hurting yourself, but you are just kidding yourself. The pain of your death or the person you kill will start a ripple effect among families, friends, co-workers, and others. And the pain is not short-lived. It will become an ache that won't go away.

So please, think this holiday season before you have too much to drink and try to drive home. How else could you get home? What could you do at a party instead of drinking? Then ask yourself - how will my family feel if they have to spend the holidays without me? Or how will I enjoy the holidays knowing I am responsible for someone else's death? These are hard questions to ask. But if you take the time to ask them, you may save someone's life, maybe even your own.

R

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# About Mothers Against Drunk Driving

MADD (Mothers Against Drunk Driving) is a nonprofit organization with over 400 chapters in the United States. MADD is a group not only for victims of drunken drivers, but also for concerned citizens. It is not a crusade against the use of alcohol. MADD's mission is to force effective and workable solutions to the drunk driving problem.

Many people are not aware of the severity of the problem of alcohol and other drug impaired driving. MADD is dedicated to educating the public about drunk driving and to changing people's attitudes. The group sponsors community awareness programs, victims assistance and provided information for people involved in criminal proceedings. This article provides a history of MADD, explains the steps you can take to prevent drunk driving, and recaps many of the programs and services available through MADD (Mothers Against Drunk Driving). After reading these pages, MADD hopes you will take a more active part in making the roads safer for all of us.

## The History of MADD

MADD was founded by California mother Candy Lightner in 1980 after her 13 year old daughter was killed by a drunken driver with four previous drunk driving offenses. An aggressive grassroots campaign resulted in California passing the toughest drunk driving laws in the country at that time. This astounding success was only the beginning. MADD soon grew into a nationwide organization with almost 3,000,000 members and supporters. Today, thousands of concerned citizens are involved in more than 400 chapters in the United States with affiliates in Canada, Australia, New Zealand, and Great Britain. MADD is made up of men and women of all ages who share a common concern for safety on our roads.

Since MADD's founding, more than 1,200 anti-drunk driving laws have been enacted nationwide. The rights of victims and survivors of alcohol and other drug-related crashes are now viewed more equitably in a criminal justice system that a few years ago paid little attention to them.

## Community Programs

MADD develops programs throughout the year to promote public awareness and raise the nation's consciousness about the dangers of alcohol and other

drug impaired driving.

Project Red Ribbon was created by MADD in 1986 to change the meaning of "tie one on." MADD asks drivers to tie a red ribbon to a visible location on their vehicles between Thanksgiving and New Year's Day to show their commitment to drive safe and sober throughout the year. Please take part in this simple but effective program during the holiday season.

"Keep it a Safe Summer" (KISS) Campaign spreads the word that summer months can be the most dangerous. MADD's family Vacation Pack is filled with safety tips and activities for the entire family. Help MADD keep it a safe (and sober) summer on our nation's roads and waterways.

"Designated Driver" is a program with a simple point: if you choose to drink, bring along a friend who is not drinking to safely drive you home. You can help promote the program by always using a designated driver and offering to be the designated driver for your friends.

*The mission of Mothers Against Drunk Driving is to stop drunk driving and to support victims of this violent crime.*

Candlelight Vigils remind us of the thousands of loved ones killed or injured in drunk driving crashes. Please attend the Candlelight Vigil of Remembrance and Hope in your community to show your support for a less violent future.

## Youth Programs

It is illegal for anyone under the age of 21 to be served or to consume alcohol in every state in the nation. Since the national minimum drinking age was implemented, the proportion of drivers under 21 involved in alcohol related crashes has dramatically declined from 28% in 1982 to 17% in 1989.

Young people today receive many mixed messages about alcohol. MADD's message to this group is clear: drinking under the age of 21 is unacceptable and illegal. MADD has developed programs to educate young people how to avoid dangerous situations involving alcohol and other drugs.



Operation Prom/Graduation is a nationwide program designed to make prom and graduation nights memorable occasions, not memorials. It focuses on promoting chemical-free messages and events for high school students. MADD provides "how to" materials to teens and parents on conducting these activities during this special time and throughout the year. Please support Operation Prom/Graduation and other sober celebrations for teens in your community.

The MADD Poster/Essay Contest invites students in grades 1-12 to use their creative skills to deliver strong messages against drinking and driving. English and Spanish language entries are welcome and local first place entries compete nationally. Contact MADD's Youth Programs Department for information and this year's theme.

The MADD Student Library is published annually to provide information about the impact of alcohol and

***Two of every five Americans will be involved in an alcohol related crash in their lifetime. In 1989, an estimated 22,415 people were killed and 345, 000 injured as the result of alcohol and other drug impaired driving crashes.***

other drugs on young people as well as the consequences of impaired driving. It includes statistics, articles on topics such as peer pressure, and a bibliography on resources for highway safety issues. Check your school library to be sure they have a current copy on file.

"Friends Keep Friends Alive!" is an educational comic book which stresses positive peer support. It also teaches children how to say "no" to drinking and riding with someone who has been drinking. It is available in both English and Spanish versions.

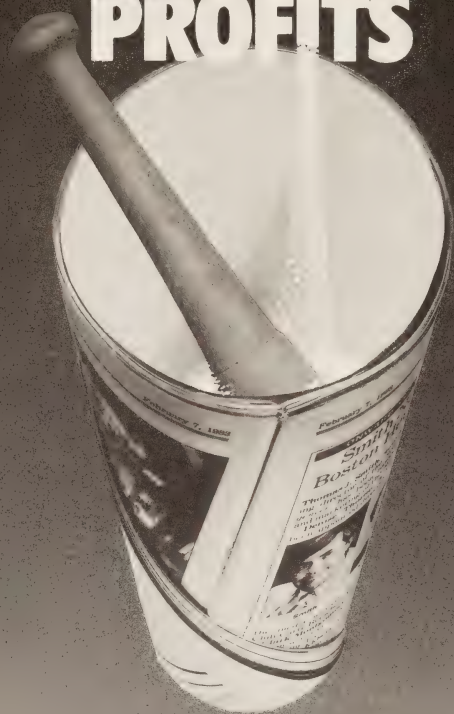
#### **Public Policy and Legislative Goals**

During its tenth anniversary in 1990, MADD renewed its focus on two primary goals: aiding the victims of alcohol and other drug related crashes and reducing the incidence of impaired driving.

Alcohol related fatalities account for approximately 50 percent of all traffic fatalities, in spite of a nearly 20 percent reduction since 1980. MADD's goal is to reduce that number by an additional 20 percent by the year 2000. MADD urges you, and all levels of government, to support this effort by focusing on objectives in these five areas.

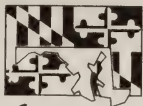
- *Youth Issues* -- Reducing the number of young people involved in alcohol and other drug impaired driving incidents requires more than enacting a minimum drinking age of 21. Alcohol free areas should be maintained for school and youth functions, young people must be educated about the hazards of alcohol and other drugs, and adults who supply alcohol and other drugs to anyone under the age of 21 must be penalized appropriately, as well as youths who commit such offenses.
- *Enforcement* -- Effective tools are available to enforce DWI laws. We must support the use of sobriety checkpoints, preliminary breath tests and passive alcohol sensors, a per se limit at an appropriate level such as .08, mandatory Blood Alcohol Content (BAC) testing when crashes result in injury or loss of life, and limits on open alcohol containers in vehicles.
- *Sanctions* -- Appropriate sanctions are effective deterrents to DWI crimes. Actions against alcohol and other drug impaired driving that have proven effective include administrative license revocation and mandatory jail time for repeat offenders. Other approaches that may reduce repeat offenses include license plate/vehicle confiscation, increasingly severe penalties for subsequent convictions, and elimination of charge reduction negotiations. Minimum-security facilities to incarcerate DWI offenders should be developed and should provide education and treatment. DWI offenses involving death or serious injury, or when the driver leaves the scene of such a crash, should be felonies and receive appropriately severe penalties. Improvement in monitoring DWI offenses from the time of arrest through the disposition of the case in court is necessary to identify and better deal with multiple offenders. This would also provide better documentation of the DWI problem and effective solutions that are being implemented on a state nation basis.
- *Self-Sufficient Programs* -- MADD advocates channeling DWI fines, fees and other assessments, including user

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periodicals to your customers, you should be. Just ask us how profitable it can be. And if you do have a magazine department, chances are your operation has outgrown it and it should be expanded. Call Jim Trosch or Pete Van Poppel today at (410)-536-4545.



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fees such as alcohol excise taxes, to ensure consistent, long term funding for comprehensive anti-drunk driving law enforcement.

- *Responsible Marketing and Service of Alcohol* -- Increased responsibility in the marketing and serving of alcoholic beverages is imperative. MADD does not call for legislated limits on beverage advertising but strongly urges the alcohol industry to monitor its own efforts to avoid any depictions of dangerous or illegal use of alcohol, including appeals to anyone under the age of 21. Any beverage promotion that encourages excessive consumption, such as "happy hours," should be ended. Programs that encourage responsibility, such as the Designated Driver campaign, should be encouraged. Alcohol advertising should also bear appropriate warnings about potential driving impairment and age 21 limits.

### Victim Issues

MADD is the largest anti-drunk driving victim assistance organization in the world. Because victims are frequently overburdened -- financially and emotionally -- from the result of alcohol and other drug impaired crashes, MADD has adopted the following public policy objectives:

- *Constitutional Amendments for Victim Rights* -- Statutory Bills of Rights are only sporadically enforced but a State Constitutional Amendment for Victim Rights would offer victims the constitutional right to be informed of, present at, and heard during the criminal justice process.
- *Bankruptcy Protection for Victims* -- Persons who kill or injure others as a result of alcohol or other drug impaired driving would not have the right to file bankruptcy in order to avoid paying restitution or civil judgements to their victims.
- *Compensation for Victims* -- Alcohol and other drug impaired crash victims would not be excluded from any State Crime Victim Compensation Program and would have the same eligibility requirements as victims of other violent crimes.
- *Dram Shop Recovery* -- Victims would have the right to seek financial recovery from establishments that irresponsibly provide alcohol to anyone under the age of 21 or serve alcohol to anyone past the point of intoxication.
- *Endangerment of Children Sanctions* -- enhanced sanctions against convicted drunk drivers would be enforced when the offender was driving with a child in the vehicle.

### MADD Victim Services

Each of the 22,415 fatalities and 345,000 injuries incurred yearly is a unique and irreplaceable individual

## How Can You Help Prevent Drunk Driving?

Drunk driving is a crime. There are several ways you can help reduce the tragic results of alcohol and other drug impaired driving.

Do not refer to incidents caused by alcohol and other drug impaired drivers as "accidents." These crashes are not accidental because they result from two clear choices: (1) to consume alcohol or use other drugs; and (2) to drive.

Never drink and drive and never allow a friend to drink and drive.

Speak out against alcohol and other drug impaired driving in your community.

Support legislation to reform drunk driving laws. Contact your local, county state and federal officials to show your interest and support.

Monitor drunk driving cases from the initial report by the arresting officer through the judicial process in our community or county. Is the process working? Report what you find to the media, your legislators and state or local MADD officials.

Designate a driver *before* you leave the house if your outing involves drinking. And, encourage your friends to always do the same.

Start educating your children early with the truth about the dangers of alcohol and other drugs.

Refuse to serve alcohol to any young person until he or she is 21 years of age. It's the law.

Respect child endangerment laws, and set a good example. Don't drink and drive, particularly with an under 21 person in the vehicle.

Remember that alcohol including beer, wine, wine coolers, and liquor is a drug which when consumed leads to impairment.

Understand that your ability to think clearly and react appropriately can be impaired by alcohol and other drugs long before you become visibly intoxicated.

Remember that cold showers, coffee or exercise do not lower the level of intoxication. Only time does that -- alcohol burns off much more slowly than it is consumed.

Report suspected drunk drivers promptly to the police.



with a name, a family, and dreams that must now go unfulfilled. Each represents far more than a faceless number to his or her family and friends, who are now caught in the tragic ripple effect set off by each crash.

Alcohol and other drug related crashes create a critical period in the lives of victims. MADD victim advocates provide emotional support to help victims cope with their grief and anger. In addition, victims receive printed materials to help them understand the grieving process and guide them through the criminal justice system. MADD brings victims together in victim support groups to discuss their feelings and futures. Victims offer each other unique understanding and reassurance.

Victims are offered a thorough explanation of the judicial process. MADD advocates clarify victim rights, accompany victims to court when necessary and follow-up on the sentencing of offenders. MADD offers 40 hour Beginning and Advanced Institutes to train victim advocates. MADD offers the Victim Information Pamphlet to inform victims about victim compensation, insurance and civil suits. The *MADDvocate* magazine provides up-to-date information for victims and victim advocates. A reproduction of the victim information provided by MADD appears in this issue of *The Maryland Pharmacist*.

Judges or probation officers order convicted drunk drivers to attend a Victim Impact Panel as a component of their sentencing. The panel is composed of three or four victims of drunk driving crashes who tell their stories simply and from the heart. The goal of the program is to enable the offenders to understand their crime from the victim's perspective and choose never again to drink and drive.

MADD chapters also refer victims to other agencies that offer financial and legal information, as well as professional counseling, as requested. To facilitate victim support, a toll-free hot line provides information at times of crises involving drunk driving.

### **MADD and You**

Grassroots activism is the force behind MADD. Your unyielding determination, commitment, energy, courage and creativity, reduces the number of deaths and injuries from alcohol and other drug related driving. You are helping us create a less violent future. Together we are making a difference because *we are in it for lives*. Be responsible for your own thinking and actions about drunk driving. Don't drink and drive. Encourage your family and friends to be responsible for their thinking and actions about drunk driving. Friends don't let friends drive drunk.

Be informed about the issue of drunk driving. Make yourself knowledgeable so that you can create conversations with others to raise their consciousness and support them in being responsible. MADD provides

numerous written materials to educate you. We are just a telephone call away.

Be actively involved at whatever level you can. If your community has a MADD chapter, volunteer your talent and time. Explore the possibility of organizing a chapter in your community, if a local chapter does not exist. Work with other resources in your community to fight alcohol and other drug related driving or create resources that are missing.

**R**

### **Clues to Drunk Drivers**

The National Highway Traffic Safety Administration offers several suggestions on identifying suspected drunk drivers. Alcohol and other drug impaired drivers frequently:

- \* Follow other vehicles too closely or drive with their headlights off at night
- \* Drink in the vehicle or drive with their face close to the windshield
- \* Weave or zig-zag across the road or drive into opposing traffic
- \* Drive slower than 10 mph below the posted speed limit
- \* Use turn signals that are inconsistent with driving actions or stop in a traffic lane
- \* Disregard traffic signals
- \* Follow the vehicle too closely the driver may stop suddenly

If possible, attempt to detain the drunk driver if he or she stops. Whether this is possible or not, you should call the nearest law enforcement agency and:

- \* Tell them you want to report a drunk driver.
- \* Give the exact location (identify the street or road and direction in which the vehicle is traveling);
- \* Give a description of the vehicle (license plate number, color, make, model);
- \* Describe how the vehicle is being driven.

# Victim Information

*There is Good Reason to be MADD*

*Adopted from MADD's "Maryland Victim Information Booklet"*

Drunk driving has killed 250,000 people in the past decade and impaired or crippled 6.5 million. It is a crime which has received inadequate treatment by the criminal justice system. This situation is contributed to by society's ambivalent attitude toward drunk driving as well as a lack of knowledge concerning alcohol and drug addiction.

MADD's mission is to change public attitudes, help the judicial system become more responsive, and support education, public awareness, and legislation. We believe we can make a difference.

## **Who is a Victim?**

A victim is a person who has been killed or injured in an alcohol or drug related crash, a family member of the person killed or injured, and anyone who has suffered property damage or monetary loss due to the actions of a drunk or drugged driver. MADD (Mothers Against Drunk Driving) helps victims through direct and emotional support. These services include: help with the judicial process, referral to proper agencies, accompaniment to court, aid in obtaining pertinent records, letter writing and preparation of Victim Impact Statements. After a death or serious injury, it is normal to feel anger and grief. MADD has support groups as well as individual phone support. Sharing these feelings is an important part of the healing process.

## **Know Your Rights**

There are many stages in the judicial process where you can and should become involved. This will be helpful to you and to the prosecution of the case.

At the scene of the crash, it is important to remember four things. When possible, remain at the scene. Obtain information about the driver. Get names of witnesses. Do not make any statements concerning fault.

After the crash, the officer will take the defendant to a Commissioner who may set bail or release the defendant. This has nothing to do with the seriousness of the case, so do not be surprised at his or her decision. Obtain a copy of the "accident" report and compare it to your recollection of the events surrounding the crash. Keep in contact with the investigating office. It is

advisable to obtain the services of a lawyer as soon as possible. Contact the Maryland Bar Association for referrals if needed. This does not obligate you to any legal action. Also, you should contact your State's Attorney's office. Many counties in Maryland have a Victim/Witness Assistant to help you. They can keep you informed of the case. Send a follow-up letter and provide a telephone where you may be reached. The prosecutor serves on behalf of the State, which means it is the State versus the defendant. It is therefore important that you keep in touch with the State's Attorney's Office. It might be helpful to the prosecution if you took pictures of the crash site or the injuries, perhaps at the hospital.

## **The Judicial Process**

Unless there was a death, all impaired driving cases will be tried in District Court on the appointed trial date unless one of several things happens.

First, the prosecutor has the discretion not to prosecute the defendant. The prosecutor gets the case after the defendant has been charged and has appeared before the Commissioner. If the prosecutor feels there is not enough evidence to obtain a conviction, the prosecutor may drop the charges. If the prosecutor goes forward with the case the defendant should arrive in court when the trial is scheduled.

If an alcohol or drug impaired driver was involved in an accident resulting in death, the case originates in Circuit Court. The State's Attorney's office must decide whether to charge the driver with homicide by motor vehicle while intoxicated or manslaughter by automobile. A prosecutor can ask for a grand jury indictment or file a criminal information. In either case the prosecutor must prove that there is probable cause the defendant committed the crime charged.

The several jurisdictions within the State of Maryland differ in their procedures for charging offenders. It is advisable that you contact your State's Attorney's Office or the attesting officer for information about charges.

In Maryland the crimes involving impaired driving are misdemeanors and not felonies, regardless of the consequences, injuries or charges. This is so even if a

death results from the accident. The crimes are punishable by imprisonment, fine, or other appropriate penalties as determined by the judge. Additionally, the MVA may suspend or revoke the driver's license in a separate proceeding following a conviction of a crime.

Victims and their advocates should realize that the State's Attorney represents the State of Maryland and all of its people. The charges have been brought against the defendant because a crime or crimes have been committed against the community. The State's Attorney does not represent the victim personally or the deceased. Criminal proceedings are conducted to penalize the offender for the crime committed against the people and are not intended to compensate the victim or the deceased's family for injuries, pain, or suffering. Civil actions may be filed for the purpose of recovering money to compensate for injuries, pain, or suffering.

The State has the burden of proof in criminal cases. This means the prosecutor must convince the judge or jury that the defendant is guilty of the crime charged beyond a reasonable doubt. The burden is not on the defendant to prove his or her innocence. Every defendant has a constitutional right not to testify.

Be aware that both the defense lawyer and the prosecutor may request postponements. Also, the defense may "pray" a jury trial which will move the case to Circuit Court. At that point, the defendant has the option to go before the jury or to let the judge decide the case.

### **The Victim Impact Statement**

Contact your State's Attorney's Office to find out if a Victim Impact Statement is appropriate in your case. If allowed, your statement should address the medical, financial, and emotional impact the crash has had on your family. A form may be requested from the prosecutor's office or from MADD. Write from your heart about the pain, but do not attack the defendant, laws or judicial system. Victim Impact Statements should be prepared and presented to the prosecutor before trial as sentencing may immediately follow trial.

### **Going to Trial**

Most injured victims and surviving families want to attend the trial although they know it will be an emotionally draining experience. Expect to hear upsetting testimony and perhaps hear the defense attorney attempt to place blame on the victim. If you feel you will lose control, it is best to leave the court room. You do not want to jeopardize the case.

If the defense attorney has summoned you as a witness, notify the prosecutor as this can be a ploy to keep you out of the court room and then not call you as a witness.

When attending the trial, whether as a witness or as a spectator, remember the following guidelines:

- Tasteful, conservative dress, and dignified conduct are important.
- Report threats or harassments to the District Attorney.
- Do not wear or display MADD insignia.
- Do not hesitate to ask friends or a MADD representative to attend court with you. You have a right to ask for support and/or guidance through what can be a difficult experience.
- Be quiet in and around the courtroom. Avoid talking in the presence of the jury, the defendant or anywhere in the courthouse where you may be overheard.
- Avoid emotional outbursts or unpleasant facial expressions in court. This may be very difficult. Be aware that you are being observed and that such

***A Good Victim  
Impact Statement  
should***

***Be 3 to 5 minutes  
oral reading time***

***Not repeat evidence  
or quote statistics***

***Highlight who the  
victim was and  
what the death has  
meant to the  
survivors***

*Continued on Page 19....*



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**—MADD—**





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outbursts could be seen as an attempt to influence the jury and potentially result in the judge asking you to leave the courtroom or even bringing contempt charges against you. If you feel the need to cry or express anger, it is best to quietly leave the courtroom, preferably with a friend, and find a safe place to do so.

- If you do not understand what is happening regarding the legal procedures, write down your questions so that you can ask a MADD representative or the District Attorney during the recess or at a later date.

### Victim As Witness

Witnesses are sometimes sequestered at a trial, so if you agree to testify, you may be instructed to wait outside the courtroom until it is time for you to take the witness stand. As a witness, you may not be allowed to observe the trial until after you have testified. You may want to ask friends and/or family to attend the trial in order to keep abreast of the proceedings.

Again, there are some guidelines to keep in mind as victim-witness:

- As a witness for the state, you will be questioned by the District Attorney and then cross examined by the defense attorney. It is important for you to listen to every question asked, and to answer directly and objectively.
- Under no circumstances should you fight or "spar" with the defense attorney, since he or she is well trained to take advantage of such a situation. You are a victim of a violent crime. Tell your story to the court or jury, be honest and objective, and let the prosecutor do the arguing.

### Judgement and Sentencing

The judge may request a pre-sentencing investigation (PSI) which is done by the Probation Department. They should also receive your Victim

## Maryland Chapters Mothers Against Drunk Driving

### Central Maryland

Anne Arundel & PG Counties  
14 Hudson Street  
Annapolis, MD 21401  
AA County 410-224-MADD (AA)  
PG County 301-970-8111 (PG)

### Harford County

PO Box 688  
Bel Air, Maryland 21015-0688  
(410) 676-MADD

### Howard County

3277 Pine Orchard Lane  
Suite 1  
Ellicott City, MD 21042  
(410) 465-5757

### Montgomery County

1010 Grandin Avenue  
Rockville, MD 20851  
(301) 294-2228

### Charles County Satellite

1 (800) 446-MADD

### Northern Maryland

Baltimore, Baltimore City  
Cecil and Harford Counties  
602 E Joppa Road  
Towson, MD 21204  
(410) 321-MADD

### Upper Eastern Shore

Caroline, Dorchester, Kent, Queen  
Annes, & Talbot Counties  
Rt. 1 Box 224-D-1  
Queenstown, MD 21658  
(410) 228-3057 (Cambridge)  
(410) 827-5000 (Queenstown)

### Lower Eastern Shore

Somerset, Wicomico & Worcester  
Counties  
1502 Riverside Drive  
Salisbury, MD 21801  
(410) 742-MADD

### Western Maryland

Allegheny, Frederick, Garrett &  
Washington Counties  
49 Summit Avenue  
Hagerstown, MD 21740  
(301) 791-MADD

### Carroll County

PO Box 1734  
Westminister, Maryland 21158  
(410) 876-MADD

### District of Columbia

1910 K Street N.W.  
Suite 400  
Washington, D.C. 20036  
(202) 659-8424

Impact Statement. It is common practice in Maryland to give Probation Before Judgement (PBJ) to first time offenders. Defendants have the right to ask for a new trial or a reconsideration of sentence within 30 days.

### Contacting a Private Attorney

The crime of drunk driving which inflicts injury or death is also a civil wrong, one for which you can sue for damages. Remember, drunk driving is no accident. Although the criminal prosecution, if vigorously pursued, may remove the drunk driver from the streets, under ordinary circumstances it will not result in your being compensated for medical or funeral expenses, pain and suffering,

or the loss of comfort, society, or support of your relative in a case involving death. For this reason, you should contact an attorney experienced in personal injury matters *as soon as possible* after the crash. This does not obligate you to any legal action but will help inform you of all avenues of justice which are available to you.

The nature of the civil action for damage depends largely on the type of injuries which were inflicted.

If the victim is injured but survives, the action is brought on behalf of the victim, who has the legal right to recover medical and hospital costs, damages for pain and suffering, damages for loss of future earnings and earning capacity.

In a crash involving fatal injuries,

a wrongful death action may be brought on behalf of the defendant's heirs and seeks to recover medical and hospital costs, funeral expenses and damages for loss to society, of comfort and support due to loss of a family member.

Contact the Maryland Bar Association, the Trial Lawyers Association, friends, or contact MADD for a pamphlet entitled, "How to Choose an Attorney". You may wish to consult more than one.

Do not sign any papers or documents, especially from the defendant's lawyer or insurance company, without consulting a lawyer.

### The Media

If you have reason to believe that situations or circumstances will prevent the case from being handled appropriately and that the public should be informed, it may be useful to contact electronic and print media. After all your efforts to assure the proper adjudication of the case have failed, and if you can document the facts, the media can sometimes encourage the District Attorney to prosecute effectively as well as to inform the public as to exactly what can happen to victims of drunk driving crashes. If you find information regarding your case is reported inaccurately, politely ask for the newspaper, radio or television station to correct the inaccuracy. Follow verbal communications up with a letter stating the inaccuracies. Keep a copy of that letter.

### Letter Writing

To paraphrase an old adage, the written word is often worth a thousand spoken words. To avoid being a victim of such responses as "I don't remember you saying...," "I was never informed...," "There are too many cases..." *be sure your information is accurate and right.* Remember other people may also write letters showing their support. Keep copies of all letters.

### Who and When to Write

*The District Attorney* During all stages of the criminal prosecution process it is important to keep the District Attorney's office informed of your address and phone numbers; your desire to be kept informed; time limits and methods by which you would like to be informed; facts and information pertinent to the investigation of the case; that you are or are not against plea bargaining; and your concern for public safety. Other people may write the District Attorney about their interest in the case.

*The Probation Officer* Again, it is important to contact the Probation Department and inform them as to your willingness and desire to be involved, how and when they can contact you, and the details of the case which emphasize its aggravated nature. Letters from others in addition to letters from the victim(s) are appropriate.

*The Judge* Letters to judges who have been involved in prosecution and sentencing of prior offenses can be important. Bear in mind that if a prior sentence was imposed in another county or state, that information may or may not be available for consideration in relation to current charges. You may find it necessary to bring such information to the attention of those involved in the current prosecution. Letters to judges involved in the prosecution of current charges should be avoided. Victims and others should not contact the judge until after the conviction and prior to sentencing and should check with the District Attorney about routing a letter through the District Attorney's office at the proper time. R

## Maryland's Driving While Intoxicated Maximum Penalties

### Manslaughter by Automobile (Gross Negligence and Death Involved)

Penalty - 10 years in jail  
Fine - \$5,000  
Points - 12

### Homicide by Motor Vehicle while Intoxicated

(.10 (BAC) and Death Involved)  
Penalty - 5 years in jail  
Fine - \$3,000  
Points - 12

### Driving while Intoxicated

(.10 Blood Alcohol Content)  
Penalty - Maximum 1 year in jail  
Fine - Maximum \$1,000  
Points - 12

### Driving While Under the Influence of Alcohol

(.07 Blood Alcohol Content)  
Penalty - 60 days in jail  
Fine - \$500  
Points - 8

### Driving On A Suspended or Revoked License

Penalty - 1 year in jail  
Fine - \$1,000

### Violating an Alcohol Restriction

Fine - \$500

### Operating a Commercial Motor Vehicle with any Alcohol Concentration in the Blood

Fine - \$500



# MADD Victim Resource Directory

## Sources for Maryland Residents

### *Domestic Abuse Victim Witness Assistance Programs*

#### **Allegany County**

No formal program  
Allegheny County State's Attorney  
30 Rear Washington Street  
Cumberland, Maryland 21502  
(301) 777-5962

#### **Anne Arundel County**

Victim Witness Assistance Center  
101 South Street  
Annapolis, Maryland 21401  
(410) 222-1897

#### **Baltimore County**

Victim Witness Assistance Unit  
401 Bosley Avenue, 5th Floor  
Towson, Maryland 21204  
(410) 887-6650

#### **Calvert County**

Victim Witness Unit  
County State's Attorney's Office  
175 Main Street  
Prince Frederick, Maryland 20678  
(410) 535-1600 ext.364

#### **Caroline County**

Victim Assistance Unit  
Caroline County State's Office  
Court House  
Denton, Maryland 21629  
(410) 479-0255

#### **Carroll County**

Victim Witness Assistance Unit  
125 N. Court Street  
Westminster, Maryland 21157  
(410) 876-7500 Baltimore Line  
(410) 857-2073

#### **Cecil County**

No formal program  
Cecil County State's Attorney  
Court House  
Elkton, Maryland 21921  
(410) 398-0200 ext. 192

#### **Charles County**

Victim Witness Assistance  
Post Office Box 3065  
La Plata, Maryland 20646  
(410) 932-3360

#### **Dorchester County**

Program pending 1993  
Dorchester County State's Attorney  
403 High Street  
Cambridge, Maryland 21613  
(410) 228-3611

#### **Frederick County**

Victim Witness Circuit Court  
Post Office Box 210  
Frederick, Maryland 21701  
(301) 694-1974

#### **Garrett County**

No formal program  
County State's Attorney Office  
Court House  
Oakland, Maryland 21550  
(301) 334-1974

#### **Harford County**

Victim Witness Assistance Unit  
Office of the State's Attorney  
Court House  
Bel Air, Maryland 21014  
(410) 638-3243  
(410) 879-3204 - Baltimore Line

#### **Howard County**

Victim Witness Assistance Unit  
Office of the State's Attorney  
8360 Courthouse Avenue  
Ellicott City, Maryland 21043  
(410) 313-2108

#### **Kent County**

No formal program  
Kent County State's Attorney  
Court House Annex  
Chestertown, Maryland 21620  
(410) 778-4600

### *Support Groups*

#### **Mid-Shore Council**

(Eastern Shore)  
PO Box 5  
Denton, MD 21629  
(800) 927-HOPE  
(410) 872-5276

#### **Victim Advocate Program**

(Montgomery County)  
401 Hungerford Drive  
Rockville, MD 20850 Suite 402  
(301) 217-1425

#### **Compassionate Friends**

(Death of a Child)  
PO Box 625  
Brooklandville, MD 21022-0625  
(410) 321-7053

#### **Victims of Homicide and Drunk Driving Support Group**

(Baltimore County)  
(410) 321-6233  
(410) 887-6650

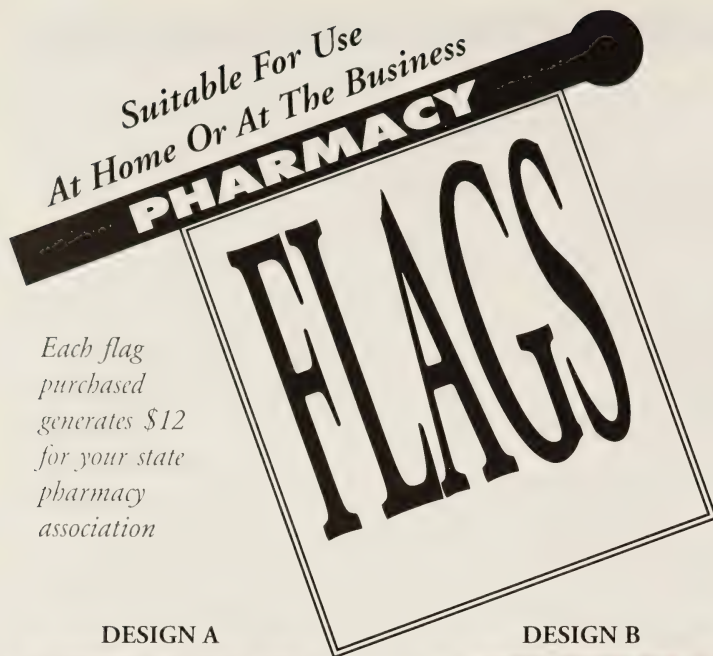
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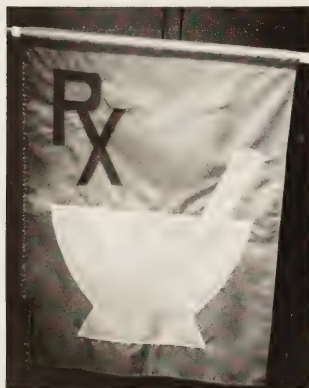
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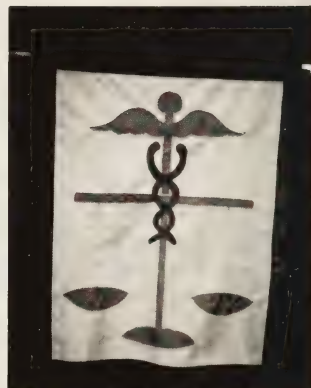
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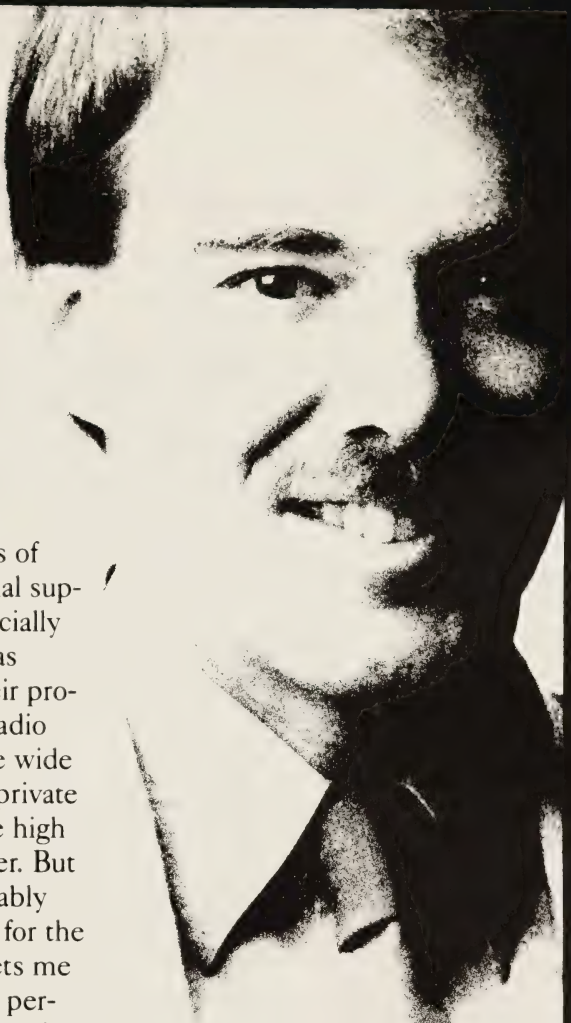
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## Facts About Teenage Drinking and Driving

- Fact** Motor vehicle accidents are the leading cause of death among persons 15-24 years of age; 45 per 100,000 died in fatal crashes in 1980.<sup>1</sup>
- Fact** More than 16,500 youths 15-24 years of age died in 1980 as a result of motor vehicle accidents.<sup>2</sup>
- Fact** More motor vehicle fatalities occurred among 15-21 year-olds on weekend evenings between 11 pm and 3 am than occurred any other time.<sup>2</sup>
- Fact** One out of every four senior high school students was at risk for alcohol-related accidents at least once during the previous year. More than half a million 10th to 12th grade students are estimated to have driven after they had a "good bit" to drink 10 or more times during the previous year.<sup>3</sup>
- Fact** The majority of persons involved in fatal motor vehicle accidents are males. In 1980, 77 percent of all youths 15 to 24 years old killed in motor vehicle accidents were males, as were 83 percent of all drivers these ages who were involved in fatal crashes.<sup>2</sup>
- Fact** The involvement of drivers in fatal motor vehicle accidents was highest (142 per 100,000 licensed drivers) among males 19 years of age.<sup>2</sup>
- Fact** Senior high school students who frequently drove cars while under the influence of alcohol were more likely than other students to be male, to be in the 12 grade, to get lower grades, to have had their first drink before 12 years of age, to get drunk at least once a week, to drink hard liquor, to drink in unsupervised settings such as cars at night and teenage hangouts, to get into trouble with their families over their drinking, and to believe they had some kind of problem with drinking. They also tended to be more tolerant of problem behavior and to be less religious than other students.<sup>3</sup>
- Fact** Traffic crashes are the number one killer of people between the ages of 5 and 34. And alcohol is involved in at least half of those crashes.<sup>4</sup>
- Fact** Two out of every 5 people will be involved in an alcohol related crash in their lifetime.<sup>4</sup>
- Fact** Each year, about 660,000 police reported crashes are alcohol related.<sup>4</sup>
- Fact** During the hours between 7 pm and 3 am on the weekends, in many parts of the country, one out of every ten cars has a drinking driver behind the wheel.<sup>4</sup>
- Fact** Drinking drivers kill their friends. Many teenage passengers who die are in cars driven by other teenagers.<sup>4</sup>
- Fact** The profiles of the people killed in alcohol related crashes:
- 20% are passengers in the drinking drivers' cars
  - 17% are people outside drinking drivers' cars
  - 11% are drinking pedestrians
  - 52% are the drinking drivers themselves<sup>4</sup>
- Fact** Not all people in alcohol related crashes die. Many are crippled or disfigured for life. There are 560,000 people injured every year in alcohol related crashes. That's an average of one person injured every minute, 60 every hour, 1,440 every day.<sup>4</sup>

### Statistical Sources

<sup>1</sup> National Center for Health Statistics (NCHS)

<sup>2</sup> Fatal Accident Reporting System (FARS)

<sup>3</sup> Research Triangle Institute (RTI)

<sup>4</sup> Mothers Against Drunk Driving (MADD)

# Personal Strategies

## *A Savvy Tax Move*

Peter A. Winer, Mayer Steinberg & Yospe



Would you consider having your cake and eating it too if you could get an income tax deduction, capital gains break, estate tax break, pass more to your heirs at your death, have an increased income and help your favorite charity, all in one fell swoop?

According to Richard Block, CPA, of Levin Zwagil & Block, "This is one very savvy tax move," which can do all of the above for you, "when you donate a highly appreciated asset to a charitable remainder trust you set up for a charity you wouldn't mind helping, while you help yourself." According to Block, the new tax law has made these trusts more popular than ever.

The reason for this renewed popularity is that the built-in gain in appreciated property donated to charity is no longer considered a tax-preference item for the alternative minimum tax under the new law. This makes the full fair market value of the asset deductible for charitable purposes. According to Steven Leimbeg, JD, "This change definitely encourages significant gifts to universities, museums, and other charitable organizations."

You might be wondering exactly what a charitable remainder trust (CRT) is. In simple terms, it is an irrevocable trust - meaning once it's created it cannot be changed. A CRT pays you an income for as long as you live. At your death, whatever is left in the trust (the remainder) goes to the charity (or charities) you originally chose. Charities could be your alma mater, church or synagogue, a museum, hospital etc.

How can you come out ahead by giving things away? Tax savings. There's no capital gains tax due on an asset you donate to charity. You receive an immediate income tax deduction even though the "remainder" will not pass to the charity until after your death. You also reduce your estate taxes because the asset you donate is not included in your estate at death. This reduces the amount that will eventually pass to your heirs, but you can easily and affordably overcome this problem by replacing the asset with life insurance. As you'll see, you can still end up with more income than you might otherwise have earned, in addition to

***How one good move can reduce your 1993 income tax, wipe out a potential capital gain, provide gain, provide you with higher income, reduce you estate tax, benefit your heirs and help your favorite charity***

your tax savings.

According to Block, there are two types of charitable remainder trusts. Both must be written for you by a qualified attorney. A Charitable Remainder Annuity Trust (CRAT) pays you a fixed amount of the initial value of the amount donated to the trust each year (no less than five percent and usually no more than ten percent). A Charitable Remainder

Unitrust (CRUT) pays you a fixed percentage (not less than five percent and also generally not more than ten percent) of the trust as valued annually.

Let's look at a case study. Dave and Barb Action are both age 60 and own a \$1 million building with a \$50,000 cost basis. If they sell the building outright, they will have \$667,500 after paying the 28 percent capital gains tax. This amount will generate \$66,750 of pre-tax annual income assuming it is invested and yields a 10 percent return. At their death, the \$667,500 would be subject to federal estate tax because the Actions have other assets and their children would receive only \$300,375, assuming a 55 percent estate tax bracket. That's a shrinkage of 70 percent from their original \$1 million asset!

Instead of selling outright, the Action's CPA suggests they transfer the property to a charitable remainder unitrust and retain a 10 percent income interest for life. Since the CRT\UT pays no tax on the sale, it has post-sale principal of \$1 million to invest for the Actions. On the basis of the same 10 percent yield, they will receive \$100,000 or pre-tax annual income. Since the remainder eventually passes to a charity, the Actions also receive a \$104,260 charitable contribution deduction on their current income tax return. If they can't use the whole deduction in the first year, they can carry forward the balance for the next four years. When the Actions eventually die, their

estate is reduced by the \$1 million (plus all of the growth which was transferred out of their estate).

If the Actions are favorably inclined towards their children, they can provide for them by establishing a separate irrevocable trust for the benefit of their heirs, and the trustee can purchase a life insurance policy on the Actions. A survivorship policy is usually the most cost-effective for this purpose. In this example the Actions' trustee purchased a \$500,000 policy, funded with annual gift tax exclusions of \$12,440. Based on the insurance company's proposal the policy will be fully funded in nine years, and their children will receive \$500,000 -- without owing any federal estate tax. A gain of over \$200,000 from what they would have received net of estate tax had the Action's sold outright.

Robert Birgen, CPA writes in the May 1993 issue of *The Journal of Taxation* that "Ultimately, everyone is better off with a CRT: the [donors], their heirs, and of course the charity or charities that will eventually receive [the remainder] when [the donors] die."

What are the downsides of this opportunity? The biggest one is fairly obvious. The trust is irrevocable. once you set it up, the trust is there to stay. And once funded, assets may not be removed.

Another issue is replacing the asset for your heirs. In order to use life insurance to do this, you must be able to qualify and pass the insurance physical exam. Often however, a

person who is uninsurable for a policy on his or her own, is able to purchase insurance under a survivorship policy, which insures two lives -- one of which may be healthy enough to offset the other's illness in the eyes of the insurance company issuing coverage.

There are a number of options, and choices to make with a CRT. You must select the payout type, amount, frequency, length of the payout and whether it will be a single or joint life annuity (payable for your lifetime or that of you and typically your spouse). In addition, there are other considerations that you would need to discuss with an attorney or CPA that will affect the operation of a CRT. Don't be put off by any technical details. Allow your legal and tax advisors to help you sort these out, and maximize your gain from the use of this savvy device.

Aside from the great personal reasons to do this don't forget how much the charity will appreciate your thoughtfulness, or about all the people your legacy will help -- in addition to your own heirs. Who say you can't have your cake and eat it too? **R**





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# Capsules

*Yesterday, Today and Tomorrow*

Peter P. Lamy, Ph.D., Sc.D., UMAB School of Pharmacy



The problem of patient non-compliance with medical instructions is age-old. It is not new. Some 2,500 years ago Hippocrates said that "the doctor should realize that patients often lie when they assert that they have taken a certain medicine."<sup>1</sup> In the early 1830's, in France, somebody raised the question "why?". Why should patients not comply with their doctor's instructions? It was thought that, at least in part, it had to do with the medicines that were used. At that time, there were only "natural" products, most often plants and plant extracts, all of which had a strong and often noxious odor and taste. Was there a way to overcome that? (As an aside, it might be interesting to note that many elderly patients do not like and/or do not believe in today's medicines, simply because "they do not taste like medicines").

## The Birth of the Capsule

When additives, such as sweeteners, proved to be of no value in improving the taste of medicines, other approaches were needed. In France, in the early 1830's, a pharmacist invented a "gelatin bubble". Hard, rigid, made of gelatin, acacia and sugar, it could be filled with a liquid and would then be sealed with another drop of liquid gelatin. This effort led to the development of a gelatin-coated pill (the forerunner of today's "gelcaps"?) and then to the two-piece capsule, much as we know it today, again in France.

Some technical difficulties hindered the capsule's widespread use.

However, in the middle 1870's these problems were solved in the United States. Around the turn of the century, two American companies (Lilly and Parke Davis) both began to manufacture gelatin capsules. Two types of gelatin were used: Type A, mainly derived from pigskins; and Type B, principally derived from animal bones. It might be mentioned that in the early 1930's, studies were undertaken in Basel, Switzerland which resulted in suggestions that certain colors would enhance the effectiveness of certain medications (the so-called Luescher Palette). Still later, the versatility of the hard-shell capsule was increased when it became possible to prevent leakage through such techniques as banding or liquid-sealing, together with the development of high resting-state viscosity fills. The use of hard capsules was mainly confined to the United States until after World War II, when their use spread world-wide.

Around the time that the problems of the two-piece capsule were solved, a soft, one-piece capsule, made of a mixture of gelatin and glycerin, was invented in France. The use of one-piece capsules has, in general, been restricted to vitamins and oils.

## Advantages of Capsules

**Hard Capsules** More often than not, unwanted binders, fillers, or artificial coloring are not needed, eliminating potential stability and interaction problems. One manufacturer claims that "tablets

break into uneven-sized particles that dissolve in a relatively confined area. Capsules (in this instance filled with an active ingredient in pelletized form) can release hundreds of tiny beads that disperse over a wide area of the gastrointestinal tract and might dissolve equally well in the acidic milieu of the stomach and the alkaline one of the small intestine, thus possibly significantly enhancing absorption of the active ingredient.<sup>12</sup> Capsules, in the past, have also been used to administer drugs rectally. Of course, they still provide the physician and pharmacist with a means to prepare an individualized dosage form for an individual patient.

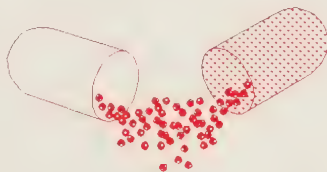
### One-Piece (Soft) Capsules

Soft gelatin capsules exhibit several advantages over other solid oral dosage forms (tablets, hard capsules) and other dosage forms such as solutions or suppositories. The main advantage, most often cited, is improved bioavailability of the active ingredient.<sup>3,4</sup> Dissolution and bioavailability have been shown to be superior to two-piece capsules and/or tablets for a host of drugs, including digoxin, chloramphenicol, prednisolone, and many others. In addition, it has been claimed that oval, round, and oblong shapes are ideally suited for oral administration and that the pliable wall of these capsules makes it easier to swallow them, possibly enhancing compliance.

### Versatility of Capsules

Both the one-piece and two-piece capsules have been used to administer

safely and effectively a wide variety of agents, often providing the only means to do so or helping to overcome specific difficulties. For example, in one uncooperative patient with Graves disease, a capsule of <sup>131</sup>Iodine was safely administered via a nasogastric tube.<sup>5</sup> Fish oil capsules have been very successful.<sup>6</sup> As the rate of long-term graft survival of renal transplants in diabetic patients has increased, patient compliance has assumed even greater importance, since non-compliance is a major cause of late graft rejection. So far, an oral solution dosage form of cyclosporine has been used to prevent graft rejection, but that solution tends to have some drawbacks which may decrease patient compliance, such as inconvenience, an oily taste, and difficulty in measuring the dose, especially among visually impaired diabetic patients.<sup>7</sup>



Two parenteral vaccines are currently used in the United States to protect against typhoid fever. The one used for the civilian population is a heat-phenol-inactivated vaccine, which is associated with a high incidence of local and systemic adverse reactions. In contrast, a live-attenuated oral vaccine produces far fewer adverse reactions. Ty21a is

available as an enteric coated capsule, recommended for persons for six years old and older. Some 450,000 doses have been administered to some 150,000 persons in Switzerland since 1984, with only mild and negligible adverse reactions reported.<sup>8</sup>

Oral vancomycin is the treatment of choice for severe colitis caused by *C. difficile*. Vancomycin oral solution has a very low pH which gives the preparation an unpleasant taste and can cause oral irritation. This may decrease patient compliance. Patients with active herpetic lesions or ulcerative stomatitis may not tolerate the oral solution. The low pH may also affect the esophagus and may exacerbate different esophageal conditions. Therefore, the solution should only be used for patients with nasogastric tubes or those unable to swallow a solid dosage form. All other patients should receive the capsule dosage form.<sup>9</sup>

### Overcoming Problems

Child non-compliance with medical recommendations is pervasive.<sup>10,11</sup> Capsules are often recommended for children, since the care (medicine)-giver does not need to measure out a liquid preparation, avoiding spills due to uncooperative patients. Furthermore, common household spoons ought not be used to measure an exact volume (they may range in volume from 4 ml to 9 ml according to some studies). Also, liquids often need shaking which is often not done, under or over-dosing the child, and still other liquid preparations simply



do not taste good enough to foster compliance.

On the other hand, youngsters may have swallowing difficulties, and programs have been developed which can teach children the necessary skill acquisition to then be able to swallow capsules. Brief, effective approaches have been reported which can be used to teach children between the age of 18 months and 16 years to swallow capsules, thus enhancing compliance.

### Why Capsules

In one survey, almost two-thirds of consumers questioned preferred a capsule to any other dosage form but only 25% of all solid oral dosage products were then available as capsules.<sup>12</sup> Another marketing research paper determined that the preference for capsules and coated tablets can be attributed primarily to the perception that capsules are easy to swallow and have no aftertaste.

### The Problem

After Tylenol® and Sudafed®, consumers needed reassurance concerning the safety of capsules. New and safer two-piece capsules were developed and, in the case of Tylenol®, the manufacturer also provided "caplets" and "gelcaps". OTC marketers, it has nevertheless been stated, should reconsider the use of two-piece capsules. FDA Commissioner Kessler has indicated that the FDA would tacitly endorse switches to non-capsule dosage forms. Capsule tampering prevention measures have been proposed by Washington State. A survey, sponsored by the Nonprescription Drug Manufacturer's Association of 1,254 adults, 239 teenagers and 596 mothers who reported on their children found that 38 percent of those questioned are "very concerned" about tampering of OTC medicines in capsule form, but 54 percent would ask for tamper-resistant packaging and 33 percent for consumer

education.<sup>13</sup>

These are interesting statistics, but it might well be that the survey did not go far enough. Thousands of elderly (and, or course, other persons) purchase food supplements in health food stores. There they might find, among many other preparations, a timed-released dietary capsule that contains 45 ingredients, including antioxidants (to offset the action of free radicals), vitamins and minerals.<sup>14</sup> Indeed, there is no doubt that the sale of encapsulated food supplements is increasing, indicating no consumer concern.

### Summary

Capsules provide a very flexible dosage form, one that can be used and has been used successfully to increase compliance, "the other drug problem". Indeed, capsules may have a bright future specifically because of their proven ability to enhance compliance with certain drugs. R

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### About the Author

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